TEST OF MASTICATING AND SWALLOWING SOLIDS: SENSITIVITY TO PARKINSON'S DISEASE SEVERITY

A Thesis Submitted in Partial Fulfilment of the Requirements for the Degree of Master of Science in Speech and Language Sciences

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Abstract

Objectives: The Test of Masticating and Swallowing Solids (TOMASS) has been proposed as a quantifiable assessment of swallowing efficiency that encompasses both oral and pharyngeal components of swallowing. This test may have clinical application as a dysphagia screening and treatment outcome measure. Reduced swallowing efficiency has been documented in patients with Parkinson's disease (PD). The literature also suggests that severity of PD motor symptoms correlates with dysphagia severity. This study aimed to determine whether the TOMASS is a sensitive tool for identifying a decline in swallowing efficiency related to the presence and severity of PD. Comparison of performance on the TOMASS with a test that had already been validated in this population, the 150 ml Timed Water Swallowing Test (TWST), might also provide further insight in to the sensitivity of the TOMASS, it's relationship with dysphagia, and application to the PD population.

Participants: Forty participants with a diagnosis of PD were evenly recruited to two groups based on severity of PD motor symptoms: mild-moderate PD and advanced PD. Classification was based on Hoehn and Yahr scale PD severity scores that were assigned to PD participants after administration of the Movement Disorders Society – Unified Parkinson's Disease Rating Scale (MDS-UPDRS) part III – motor examination. Age and gender-matched controls for each group were also recruited.

Method: Each participant completed the Eating Assessment Tool (EAT-10) survey. Participants then completed two trials of a 150 ml TWST and two trials of the TOMASS whilst being video recorded. The order in which these tests were presented was counter-balanced. Total time taken, number of bites, number of masticatory cycles, and number of swallows were recorded for solid food trials. Total time taken, number of swallows, and volume swallowed were recorded for fluid trials. To establish intra- and inter-rater reliability, 20% of the video-recordings were randomly selected and reviewed by the primary researcher and two final-year speech-language therapy (SLT) students.

Results: High intra-rater reliability (ICC > 0.8) was achieved across all measures on the TOMASS and the TWST. Similarly, high inter-rater reliability (ICC > 0.8) was achieved across all measures on TWST and TOMASS except the number of swallows on the

TOMASS, which had only moderate agreement (ICC=0.67). There were no significant differences in TOMASS measures between the mild-moderate PD and advanced PD groups. There was, however, a longer total time required for the mild-moderate PD group compared to the control group and a longer total time and an increased number of swallows, masticatory cycles, and bites in the advanced PD group compared to the control group on the TOMASS. There was a positive correlation between increasing PD severity as indicated by higher MDS-UPDRS scores and masticatory cycles. Positive correlations were found between TOMASS and TWST for total time and number of swallows.

Conclusions: The TOMASS is a sensitive measure of reduced solid food swallowing efficiency caused by PD. The presence of PD rather than severity appears to have a stronger influence on reduced swallowing efficiency but PD severity does appear to play a role. Despite the differences in TOMASS variables between groups, the effect sizes were small, which reduces its clinical applicability. However, the sample of patients recruited in this study did not represent the severity of patients clinically presenting for swallowing evaluation and population bias can explain these small effect sizes. The number of masticatory cycles appears to be the most sensitive measure in response to changes to PD severity but it is unclear what impact dentition has on this measure. The TOMASS is a solid food correlate to the TWST, as expected, and there is a relationship between decreased efficiency in completing the TOMASS and the presence of dysphagia. Further research to validate the TOMASS is required before conclusions can be drawn around its clinical application.

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Table of Contents

Preface

This research was carried out between November 2013 to January 2014 at the Kingston Centre, Monash Health, Melbourne, Australia and April 2014 to July 2014 at the New Zealand Brain Research Institute, Christchurch, New Zealand. Ethical approval for this research was gained from the Monash Health and University of Canterbury human research ethics committees.

This research was completed under the supervision of Associate Professor Maggie-Lee Huckabee and Professor Richard Jones. Additional supervisory support was received from Professor Tim Anderson from April 2014.

This thesis conforms to the referencing style recommended by the American Psychological Association Publication Manual (6^{th} edition) with spelling in New Zealand English.

The preliminary design of this research project was presented at the Biomouth conference, Dunedin, New Zealand, October 2013.

List of Abbreviations

TOMASS	Test of Masticating and Swallowing Solids
PD	Parkinson's disease
TWST	Timed Water Swallowing Test
WST	Water Swallowing Test
EAT-10	Eating Assessment Tool
MDS	Movement Disorders Society
UPDRS	Unified Parkinson's Disease Rating Scale
SLT	Speech-Language Therapist
ICC	Intraclass Correlation Coefficient
CSE	Clinical Swallowing Examination
UES	Upper Oesophageal Sphincter
VFSS	Videofluoroscopic Swallowing Study
VEES	Videoendoscopic Evaluation of Swallowing
SWAL-QOL	Swallowing Related Quality of Life survey
EMA	Electromagnetic Midsagittal Articulography
sEMG	Surface Electromyography

Chapter 1. Introduction

Assessment of swallowing function is necessary in adult populations at high risk of swallowing impairment to facilitate treatment planning and reduced associated illness and morbidity. Impairment in swallowing function, known as dysphagia, occurs in over 68% of individuals with Parkinson's disease (PD) (Coelho et al., 2010; Kalf, de Swart, Bloem, & Munneke, 2012). The presence and severity of dysphagia increases as PD severity increases (Kalf et al., 2011; Umemoto, Tsuboi, Kitashima, Furuya, & Kikuta, 2011) and patient report is not a sensitive measure of identifying the presence of dysphagia in the PD population (Kalf et al., 2012; Manor, Giladi, Cohen, Fliss, & Cohen, 2007). Reduced swallowing efficiency in the PD population has been reported (Kanna & Bhanu, 2014; Miller et al., 2009) with reduced swallowing speed associated with increased risk of developing aspiration pneumonia (Lin et al., 2012). Although both the oral and pharyngeal phases of swallowing are impacted by PD (Baijens et al., 2011; Nagaya, Kachi, & Yamada, 2000), oral phase dysphagia may be more prevalent in the PD population than pharyngeal phase dysphagia (Lam et al., 2007).

Clinical swallowing examinations (CSE) conducted by speech and language therapists are primarily subjective, resulting in insufficient reliability (McCullough et al., 2000) and reduced sensitivity and specificity in diagnosing dysphagia (Splaingard, Hutchins, Sulton, & Chaudhuri, 1988). Increasing the objectivity of the CSE with more quantifiable assessment measures can improve the reliability of this assessment.

A timed water swallowing test (TWST) has been established as a reliable quantifiable clinical swallowing assessment (Nathadwarawala, Nicklin, & Wiles, 1992) that is sensitive to changes in swallowing function resulting from Parkinson's disease (Miller et al., 2009) and other neurological disorders (Hughes & Wiles, 1996). A similar timed test of solid food swallowing, the Test of Masticating and Swallowing Solids (TOMASS), was developed by Athukorala, Jones, Sella, and Huckabee (2014), because water swallowing may be less sensitive to oral phase swallowing impairments and cannot assess aspects of solid food ingestion such as mastication. Limited research has been published on the TOMASS (Athukorala et al., 2014; Battel & Huckabee, 2014a, 2014b; Huckabee, McIntosh, &

Apperley, 2014) and further investigation into the reliability and sensitivity of the TOMASS in the context of dysphagia and specific patient populations is required for validation.

This study has been designed to investigate the sensitivity of the TOMASS in response to swallowing impairment associated with PD and increasing PD severity. Additionally, this study has been designed to determine the extent to which the TOMASS is a solid-food swallowing correlate to the TWST. Therefore the following research questions are addressed:

1. Is the TOMASS a sensitive assessment tool for detecting reduced swallowing efficiency that may result from the presence of PD?
2. Is the TOMASS a sensitive assessment tool for detecting reduced swallowing efficiency that may result from increased severity of PD motor symptoms?
3. Will participant performance on the TOMASS correlate with performance on the TWST, with performance on both tests decreasing as PD severity increases?

Information on the reliability of the TOMASS and the relationship between the TOMASS and TWST performance has been gained through the design of this study.

Chapter 2. Literature review

2.1 Swallowing

Swallowing is often conceptualised as consisting of three phases: oral, pharyngeal, and oesophageal. However, for ingestive swallowing, this process begins with a pre-oral phase even before the bolus touches the lips. This pre-oral phase of swallowing involves cortical processing of a bolus, based in part on sensory information received from the olfactory and optic cranial nerves, to develop an appropriate swallowing plan. The three primary phases of swallowing and the swallowing biomechanics of each are described in further detail in the following sub-sections.

2.1.1 Oral phase

The oral phase of swallowing is largely voluntary and involves coordinated labial opening and closure, mastication and lingual movements to receive, maintain, and manipulate the bolus in the oral cavity. The trigeminal, facial, and hypoglossal nerves, the pharyngeal plexus (components of the glossopharyngeal and vagus nerves), and ansa cervicalis (cervical spinal nerves 1 and 2) are involved in motor aspects of these movements. Sensory feedback during this phase is provided through the trigeminal, facial, and glossopharyngeal nerves (Jean, 2001).

Mastication involves rapid and regular jaw motion with distinct open and close cycles. Movement of the jaw also results in hyoid movement. A general trend of the hyoid retracting downward as the jaw closes has been documented (Palmer, Rudin, Lara, & Crompton, 1992).

On completion of mastication and oral preparation of a solid bolus, a specific sequence of movements has been observed to facilitate transfer of the bolus into the pharynx. The hyoid moves posteriorly and inferiorly as the jaw closes. After the hyoid and jaw reach this retracted position, the back of the tongue which was raised to meet the palate, now drops allowing space for bolus entry into the pharynx. The hyoid and tongue then move sharply upward and forward while the tongue compresses the bolus against the palate (Palmer et al., 1992). As the jaw opens slowly, tongue to palate contact reaches peak pressure (Hori, Ono, & Nokubi, 2006) and the tongue progresses backward, squeezing food back along the palate and

into the oropharynx. Rotational movement of the tongue occurs during this bolus transfer, with prolonged tongue to palatal contact on the non-masticatory side (Hori et al., 2006).

Transfer of larger solid boluses from the oral cavity to the pharynx can be segmented. Several transfer cycles may occur during mastication and oral preparation prior to the bulk of the bolus being transferred and the initiation of a swallow. Mastication continues and appears largely uninterrupted by segmented bolus transfer. Anterior displacement of the hyoid is greater during swallowing than during chewing or bolus transfer. Swallowing onset occurs in the closed phase of a masticatory cycle (Palmer et al., 1992).

Differences in food textures have been found to result in differences in time required to orally prepare food for swallowing, time between the bolus entering the pharynx and swallow onset, and time taken between swallows. Liquid ingestion requires minimal oral preparatory time with prompt swallowing onset on transfer into the pharynx, allowing for a more rapid and reflexive swallowing plan (Palmer et al., 1992). Oral preparatory time tends to increase with increasing density of solid foods (Palmer et al., 1992) and a longer swallowing duration also occurs with denser boluses (Cassiani, Santos, Parreira, & Dantas, 2011; Palmer et al., 1992).

2.1.2 Pharyngeal phase

The pharyngeal phase begins with the onset of swallowing. This usually occurs on active transfer of the bolus from the mouth into the pharynx. When a pharyngeal swallow is triggered, the mylohyoid muscle in the floor of mouth is the first muscle to become active (Jean, 2001). A rapid sequential but overlapping activation and relaxation of the muscle pairs involved in pharyngeal swallowing follows. Consequently, the following is achieved:

- anterior hyoid movement which in turn assists with epiglottic deflection and upper oesophageal sphincter (UES) opening
- velopharyngeal closure
- supraglottic shortening
- vocal fold adduction
- base of tongue to posterior pharyngeal wall contact
- pharyngeal shortening
- sequential contraction of the pharyngeal muscles superiorly to inferiorly squeezing the bolus through the open UES

- UES contraction on completion of the swallow as the hyoid returns to rest.

The trigeminal, facial, vagus, and glossopharyngeal nerves, as well as the pharyngeal plexus and ansa cervicalis, are all involved in these motor processes. Sensory input to allow for airway protection and clearance is provided through the pharyngeal plexus and superior laryngeal nerve of the vagus or the recurrent laryngeal nerve at the carina (Jean, 2001).

2.1.3 Oesophageal phase

The oesophageal phase begins once the bolus has passed through the upper oesophageal sphincter. The bolus is then transferred in a peristaltic wave (Jean, 2001). Completion of the pharyngeal and oesophageal phases of swallowing occurs within 0.6 to 1.0 s (Jean, 2001).

2.2 Dysphagia Assessment

Considering the complex, precise, and rapid nature of swallowing, it is not surprising that swallowing can become impaired. Impairment in swallowing is known as dysphagia. Although dysphagia can present overtly through coughing, choking, or discomfort when eating and drinking, an individual may not be aware of the presence of dysphagia. Impairment to sensation and/or cognition can result in reduced awareness. If sensory input is reduced then airway protection mechanisms, such as reflexive coughing, may not be triggered in response to the entry of food and/or fluids into the airway. This is known as silent aspiration. Aspiration can result in serious health consequences such as pneumonia. Aspiration pneumonia presents a leading cause of infection or death and is associated with many neurological illnesses (Fernandez & Lapane, 2002). Swallowing assessment in populations considered to be at high-risk of developing dysphagia is required in order to avoid serious health and psychosocial consequences and apply appropriate management strategies.

Dysphagia is initially, and at times solely, assessed using a subjective clinical swallowing examination (CSE) involving a medical file review, case history, oral motor examination, and oral trials of a range of bolus textures and viscosities. A CSE is used to determine the risk of dysphagia and need for instrumental swallowing assessment, such as videofluoroscopic

swallowing studies (VFSS) and video-endoscopic evaluation of swallowing (VEES) are appropriate.

Instrumental assessments of swallowing such as VFSS and VEES are considered to be 'gold standards' for assessment of swallowing function as they allow for visualisation of swallowing physiology and bolus flow as well as identification of silent aspiration (Wu, Chang, Wang, & Lin, 2004). As these assessments can be expensive and invasive to perform, it is not feasible or appropriate to perform these assessments on every patient suspected of, or at risk of, dysphagia. Consequently, CSE is the only method used for identification of dysphagia in many patients. The subjective nature of the CSE presents an issue relating to inter- and intra-rater reliability.

Reliability of performing this assessment is important because the CSE is the basis for further management of dysphagia. McCullough et al. (2000) investigated the inter- and intra-rater reliability of the components of the CSE. Three experienced speech-language therapists (SLTs) used the CSE to assess the swallowing of twenty patients who were six-weeks post-stroke. Assessment of each patient was performed twice across two consecutive days. The SLTs assessed in pairs, with one of the three SLT's assessing the same patient twice and the other two assessing this patient only once. Adequate inter- and intra-rater reliability was found in 28% of the history measures, 58% of the oral motor measures, 60% of the voice measures, and 15% of the swallowing measures. Overall, inter- and intra-rater reliability for CSE was 44%. This well-designed study, conducted by experienced clinicians, revealed that inter- and even intra-rater reliability of the CSE is unsatisfactory.

Splaingard et al. (1988) investigated the validity of the CSE for detecting aspiration in 107 rehabilitation patients by comparing the CSE findings to those of VFSS. They found that 40% of the patients aspirated on VFSS and silent aspiration was observed in half of these patients. Only 42% of the patients found to aspirate on VFSS were identified through CSE, with some of these patients having been categorised to be within normal limits through CSE. Only three of the ten patients found by VFSS to have profound dysphagia were identified as such based on CSE and two of these had not been determined to aspirate at all. The authors of this study approached analysis of the CSE by breaking it into a five-point severity scale and also did not control for level of clinical experience, which may have negatively impacted on the sensitivity of the CSE.

These results indicate that the reliability and validity of CSE is generally insufficient. The oral trial component of the CSE was found to be the least reliable component of the CSE (McCullough et al., 2000). The subjective nature of the oral trials component of the CSE likely contributes to poor reliability. Therefore, more objective quantifiable measures for assessing swallowing would be of considerable value.

2.2.1 Adjuncts to the clinical swallowing examination

A number of adjuncts to the CSE have been introduced over the years in an attempt to increase the reliability and validity of this assessment. The following discussion focuses on those adjuncts that relate specifically to the oral trial component of the CSE.

2.2.1.1 Cervical auscultation

Cervical auscultation allows for assessment of the sounds of swallowing and swallowing-related respiration with amplification of these sounds provided through a stethoscope. This technique has shown some merit in offering information to clinicians regarding the presence or absence of dysphagia and aspiration during swallowing trials (Bergstrom, Svensson, & Hartelius, 2013; Borr, Hielscher-Fastabend, & Lucking, 2007; Leslie, Drinnan, Finn, Ford, & Wilson, 2004; Stroud, Lawrie, & Wiles, 2002; Zenner, Losinski, & Mills, 1995) and may assist in the sensitivity or specificity of the oral trial component of the CSE. However, this technique is highly subjective and reliant on the individual's level of skill and training in this technique and, hence, suffers from the same subjective criticisms as the CSE itself. Even professionals trained in this technique are highly variable in their interpretation of the same swallowing sounds (Borr et al., 2007; Leslie et al., 2004; Stroud et al., 2002) and often over-identified elderly swallows as being dysphagic (Borr et al., 2007). Although there are two or three distinct sounds related to oral pharyngeal swallowing, the physiologic or bolus-related causes of these sounds remain unclear, with a high degree of inconsistency among non-dysphagic swallowers reported (Leslie et al., 2007; Spadotto et al., 2012).

2.2.1.2 Pulse Oximetry

Pulse oximetry measures arterial blood oxygenation. When paired with oral trials, it has been employed as an adjunct to the CSE to potentially detect aspiration. One theory behind this application, is that reflexive bronchoconstriction occurs in response to aspiration resulting in a drop in blood oxygenation (Bergstrom et al., 2013). This technique provides quantitative

information regarding blood oxygenation changes but the link between blood oxygenation and swallowing or aspiration is unclear. As safe swallowing requires a period of apnea, a drop in oxygen saturation during this task may reflect the individual's tolerance of interruptions to their respiration rather than aspiration or dysphagia. Reduced oxygen saturation was found to have a greater association with the presence of a respiratory illness or neurological disorder rather than the occurrence of aspiration (Colodny, 2001). Early studies investigating the use of this technique paired with oral trials reported that pulse oximetry had a high sensitivity and specificity in detecting aspiration (Collins & Bakheit, 1997; Lim et al., 2001). A later study with a stronger design found that a drop in oxygen saturation had a low sensitivity and specificity in detecting aspiration (Wang, Chang, Chen, & Hsiao, 2005). This finding was supported by further research by Ramsey, Smithard, and Kalra (2006) who paired pulse oximetry with a modified CSE. They found neither a drop in oxygen saturation alone nor paired with the CSE was adequate to identify aspiration risk as later determined by VFSS. Although potentially offering an objective measure to the CSE, the relationship between swallowing and oxygen saturation remains unclear and is therefore of limited value for increasing the reliability or validity of the CSE.

2.2.1.3 Water swallowing tests

A 3-oz water swallowing test (WST) was introduced by DePippo, Holas, and Reding (1992). Patients were asked to drink 90 ml of water from a cup without interruption. It was hypothesised that a larger standardised volume of fluid would be more likely to elicit a cough response than previous fluid trials used in the CSE and would, therefore, be more sensitive to identifying aspiration. The sensitivity and specificity of this test in identifying aspiration has been investigated by comparing outcomes with VFSS (DePippo et al., 1992) or VEES (Leder, Suiter, & Green, 2011; Suiter & Leder, 2008). Reported sensitivity of this test ranges from 76% (DePippo et al., 1992) to 100% (Leder et al., 2011) but specificity is low. The studies reporting the highest sensitivity contained a number of limitations including failure to employ any blinding methods between VEES examination and water swallow trials with the VEES administered prior to the WST. The examiners therefore knew if a patient aspirated before administering the aspiration screening test. The criteria used to determine a fail on the WST included cough, wet voice, and an inability to complete the test, allowing a large amount of subjectivity in determining pass or fail. There was also no measure of inter-rater reliability employed (Leder et al., 2011; Suiter & Leder, 2008).

A blinded study comparing water swallowing tests and VEES found that the perception of 'wet voice' is not a reliable indicator of aspiration or penetration (Warms & Richards, 2000). Wu et al. (2004) found that coughing, choking, and post-swallow wet-hoarse voice, was a poor clinical predictor of dysphagia, with a sensitivity of 47.8% in a 100 ml water swallow test, particularly failing to detect silent aspirators. Miles and Huckabee (2013) found that interpretation of the presence or absence of a cough is subjective resulting in only fair inter-rater reliability. Water swallowing tests, therefore, when applied for the purpose of identification of aspiration, have conflicting validity and lack quantifiable measures required for adequate reliability.

2.2.1.4 Timed water swallowing tests

A timed component to the WST has also been introduced, allowing for increased objectivity and a quantifiable measure of swallowing efficiency. There are several derivatives of a timed water swallow test (TWST). Nathadwarawala et al. (1992) investigated the reliability and validity of a 150 ml TWST. High inter- and intra-rater reliability and consistency in an individual's performance from one trial to the next, even when variations in flavour and temperature were introduced was reported. However, reliability data for timing of this test was established on very small numbers of healthy subjects. Normative data for swallowing speed was established using 101 healthy subjects. A dysphagia questionnaire was used to determine the presence or absence of a perceived swallowing problem in 81 individuals with a neurological impairment. A slow swallowing speed (<10 ml/s) was found to have a sensitivity of 96% and specificity of 69% in identifying the presence of perceived dysphagia.

Hughes and Wiles (1996) assessed swallowing efficiency using another derivative of a TWST in 181 healthy controls aged between 18 to 91 years and in 30 patients with motor neuron disease. They compared the impact of age, sex, height, and neurological impairment on average bolus volume, average time per swallow, and swallowing capacity (ml/s). A clearly defined procedure for this assessment was outlined, allowing for this test to be reliably repeated by both clinicians and researchers. A number of bolus volumes were presented, including 150 ml, for which normative data were gained. Those with motor neuron disease who reported the presence of dysphagia displayed reduced swallowing efficiency compared to those who did not report dysphagia and the controls. Differences in average swallowing capacity were observed across age, gender, and height with greater swallowing capacity documented in younger age, males, and increased height.

Wu et al. (2004) validated a 100 ml TWST against VFSS in 59 patients suspected of having dysphagia. Reduced swallowing speed on the TWST had a high sensitivity but reduced specificity as an indicator of dysphagia as determined by VFSS. The presence of coughing or choking during this TWST had high specificity but reduced sensitivity in detecting penetration or aspiration. When results of this TWST were combined with the presence of choking, a sensitivity of 85.5% and specificity of 91.7% for identifying the presence of dysphagia using the 100 ml TWST was reported.

With the introduction of objective measures to oral fluid trials in the form of a TWST, the reliability and validity of the CSE increased. However, this test offers limited information about the oral phase of swallowing and the CSE would also benefit from an objective measurement of swallowing solid foods.

2.3 Test of Masticating and Swallowing Solids (TOMASS)

The TOMASS was developed as a solid bolus swallowing correlate to the TWST by Hughes and Wiles (1996). The TOMASS allows a quantifiable measure that is inclusive of the oral preparatory phase of swallowing which is not challenged by fluid swallowing tests. Patients are asked to eat a single Salada™ cracker 'as quickly as is comfortably possible' and to indicate they have finished by stating their name. The number of bites, masticatory cycles, and swallows and the total time taken to complete this task are recorded. Analyses are conducted on both this raw data and derived measures of masticatory cycles per bite, swallows per bite, time per bite, time per masticatory cycle, and time per swallow.

Normative data on the TOMASS were established by Huckabee, McIntosh, Fuller, and Curry (2015) in 84 healthy adults, evenly distributed by sex across four age groups ranging from 20 years to over 80 years. Each participant performed two TOMASS trials. As the Salada™ cracker is not commercially available worldwide, a further normative sample of 80 participants was established for the Nabisco Saltine™ cracker. Both crackers are almost identical in size, weight, and ingredients but comparisons between TOMASS performance revealed differences between cracker groups in all raw data and calculated measures, with the exception of number of bites and time per swallow. As a trial effect was identified, the first trial was used for all analyses as this would be the most clinically feasible application. This

study indicated that normative data would be required for each variation of TOMASS cracker used. Age and sex differences were found for all raw data measures across both cracker types. Reduced efficiency on all TOMASS raw data measures with increasing age was seen in both normative samples. Increasing age was associated with both increased time and an increase in biomechanical movements in completing the TOMASS. Males displayed greater efficiency than age equivalent females with fewer bites, chews, and swallows as well as a shorter time taken to complete the TOMASS as reflected by the all raw data measures.

A further sample of 40 healthy adults was later recruited to establish test-retest and inter-rater reliability data for the TOMASS (Huckabee et al., 2015). The Salada™ cracker was used in this study. Participants completed two TOMASS trials three times across three consecutive days. Two raters were present during one of these three sessions and each rater independently collected the four raw data TOMASS measures. Participants were offered a sip of water between TOMASS trials to eliminate any dry mouth or oral residual that may have resulted from the first TOMASS. Despite this, a within-session trial effect was still observed with more masticatory cycles, swallows, and a longer total time seen across the second trial. Inter-rater reliability was almost perfect (ICC > 0.98) for all measures and test-retest reliability across sessions was also high with ICC values ranging from 0.83 to 0.98.

The strong reliability data now established for the TOMASS reinforces the objective nature of this assessment and the normative data available for the TOMASS thus far presents a normal range to compare patient performance to during clinical use. However, validation of the TOMASS is required to ensure that the TOMASS is a sensitive measure of changes in swallowing efficiency and the presence of dysphagia. Use of the TOMASS during the CSE would increase reliability if the TOMASS is found to be a valid dysphagia assessment tool.

A preliminary TOMASS validation study was completed by Apperley, McIntosh, and Huckabee (2015) to assess whether the TOMASS is sensitive to changes in oral function. The TOMASS was completed by 10 healthy adults prior to, immediately after, and one hour after application of a topical oral anaesthetic gel. A standardised amount of oral anaesthetic was applied to the tongue blade using a syringe and distributed around the oral cavity by participants. Differences in the raw data TOMASS variables of masticatory cycles and total time as well as the derived measures relating to these variables were observed between the baseline and oral anaesthesia conditions. These differences had resolved within one hour after

anesthesia.

Findings from the validation study indicates that the TOMASS is sensitive to changes in oral function and may be a sensitive dysphagia assessment tool. However, further research into the sensitivity of the TOMASS to impairment in specific populations is indicated for establishing validity. The present study is one of a number of studies designed to investigate the sensitivity of the TOMASS for use within the Parkinson's disease (PD) population.

2.4 Parkinson's disease

PD is a chronic, progressive, neurological disorder of the central nervous system. An estimated prevalence rate for PD is 1% of the population over 60 years old (Snow & Macdonald, 2013). Studies of similar design report incidence rates of 16 to 19 PD cases per 100,000 individuals per year (Caslake et al., 2013; Twelves, Perkins, & Counsell, 2003). Primary symptoms of PD include tremor, rigidity, bradykinesia (slowness of initiation of voluntary movement with progressive reduction in speed and amplitude of repetitive actions), and postural instability (Hughes, Daniel, Kilford, & Lees, 1992). These symptoms largely impact on mobility. However, PD can also impact other functions such as speech, swallowing and cognition. PD presents differently between individuals, with differing degrees and areas of motor and neurological impairment. PD can be difficult to diagnose as symptoms of Parkinsonism are not always caused by PD (Snow & Macdonald, 2013).

2.4.1 Neurological basis of Parkinson's disease

Lewy bodies and/or Lewy nutrites, created by a build up of alpha-synuclein protein, are clear biological indicators of the presence of PD on autopsy and differentiate PD from other progressive neurological disorders (Mu et al., 2013), although some individuals who clinically present with PD do not display these markers (Berg et al., 2014). These Lewy bodies and Lewy nutrites, which cause neuronal death, identify which structures are affected as part of the disease process (Mu et al., 2013) and the nature of disease progression (Braak et al., 2003). The first signs of PD are found to appear in the brainstem, with a gradual progression through the midbrain and eventually in the cortical areas (Braak et al., 2003).

PD is often not symptomatic until the disease has progressed beyond the midbrain (Braak, Ghebremedhin, Rub, Bratzke, & Del Tredici, 2004). This may be due to increased effect on

the substantia nigra, which produces the neurotransmitter dopamine. When the neurons containing this neurotransmitter die, tremor, rigidity, bradykinesia, postural instability, and other motor impairments characteristic of PD occur.

2.5 Parkinson's disease and dysphagia

2.5.1 Prevalence of dysphagia in Parkinson's disease

There are mixed reports relating to the prevalence of dysphagia in PD. Kalf et al. (2012) conducted a meta-analysis of studies looking at the prevalence of dysphagia in people living in community-based dwellings with PD. Oral-pharyngeal dysphagia was found to be present in at least one third of this population and an individual with PD was three times more likely to have oral-pharyngeal dysphagia than a healthy age-matched control (Kalf et al., 2012). This figure was also reflected in a questionnaire-based study of 75 PD participants conducted by Walker, Dunn, and Gray (2011). Dysphagia prevalence rates increase as disease severity increases (Kalf et al., 2011; Kalf et al., 2012; Lam et al., 2007; Umemoto et al., 2011; Walker et al., 2011). Prevalence of dysphagia in PD is likely to be higher than reported as institutionalised individuals with a higher degree of dependence or disability were not included in the studies reporting this rate.

A questionnaire was provided to 50 individuals with late stage PD by Coelho et al. (2010) with 68% of respondents reporting symptoms of dysphagia. Prevalence rates may be even higher than this as Kalf et al. (2012) noted that reported prevalence appeared dependent on assessment technique, with dysphagia identified less frequently when individuals were required to self report, for instance through questionnaires, as opposed to dysphagia being identified through clinical or instrumental assessment (Kalf et al., 2012; Manor et al., 2007). This is reinforced by studies that document aspiration in individuals with PD who reported no dysphagic symptoms (Ali et al., 1996; Nagaya et al., 2000).

2.5.2 Relationship between dysphagia and Parkinson's disease severity

There is a developing body of evidence linking the presence and severity of dysphagia with increased severity of PD. This relationship has been investigated through subjective and objective dysphagia assessment.

A prospective study of 45 participants with PD ranging from modified Hoehn and Yahr stage II to stage V was conducted by Lam et al. (2007) in order to determine clinical predictors of oral-pharyngeal dysphagia diagnosed by VFSS. Six participants were rated to have severe oral-pharyngeal dysphagia, defined by severely impaired oral bolus manipulation and transport or the presence of any aspiration. Four of these six participants had silent aspiration. Hoehn and Yahr severity was higher and body mass index lower in those participants found to have severe oral-pharyngeal dysphagia. There were no other differences in participant demographics between those with and without severe dysphagia. This finding was reinforced by Walker et al. (2011) who found that a strong correlation existed between severity of impairment of gross motor skills and the presence of dysphagia but no correlation between dysphagia and time since diagnosis, age, or gender. Self-reported difficulty in keeping food or drink in the mouth was also found by Lam et al. (2007) to be a predictor of severe dysphagia in this small sample size. A higher percentage of swallowing abnormalities found on VFSS in these participants occurred in the oral rather than pharyngeal stage of the swallow. Kalf et al. (2011) validated the Radbound Oral Motor inventory for Parkinson's disease, a five point scale for self-rated difficulties with speech, swallowing and drooling in PD. Higher ratings of impairment in this scale corresponded with higher PD severity ratings on the Hoehn and Yahr scale and the UPDRS motor examination.

The specific relationship between disease severity and oral-phase dysphagia severity has been objectively investigated by Umemoto et al. (2011). Disease severity was assessed using the Hoehn and Yahr scale and dysphagia was quantitatively assessed using VFSS with a gelatine cube bolus. Assessment was conducted on 30 patients with PD during the "on" phase of levodopa medication. Participants were recruited into two even groups: mild-moderate PD (Hoehn and Yahr stage II and III) and severe PD (Hoehn and Yahr stage IV and V). There was no difference in levodopa dose between groups. Results indicated that disease severity correlates with presence and degree of dysphagia, with longer oropharyngeal transit times, slowed speed of mandibular movement and reduced tongue pressure in the severe PD group compared to the mild-moderate PD group. No difference in speed of tongue movement was found between groups.

Further objective assessment of swallowing and the relationship with PD severity was completed by Kanna and Bhanu (2014) who compared Hoehn and Yahr and UPDRS part III severity ratings with efficiency in completing a TWST. They reported correlations between

reduced efficiency in the derived water swallowing parameters in patients scoring more than 30 in the UPDRS part III motor examination and those with Hoehn and Yahr stage III or higher. However, the distribution of participants within each severity rating is unclear and exact p-values are not provided. Additional relationships between reduced swallowing efficiency and disease duration of five or more years, and scores on the mini mental-state examination lower than 26 were also reported.

2.5.3 Consequences of dysphagia in Parkinson's disease

One of the most serious consequences of dysphagia in PD is pneumonia. Pneumonia is the most common cause of death in nursing home residents with PD (Fernandez & Lapane, 2002). The highest risk of death is specific to those diagnosed with aspiration pneumonia (Fernandez & Lapane, 2002). However, the presence of aspiration alone does not result in aspiration pneumonia. A number of contributing factors including dependency for feeding and poor oral hygiene have been identified (Langmore et al., 1998). Individuals with PD are likely to become more physically dependent and more dysphagic as the disease progresses, thus increasing their risk of developing aspiration pneumonia.

Dysphagia can also result in other serious health consequences such as dehydration and malnutrition. Dehydration has been associated with the use of thickened fluids (Robbins et al., 2008), which is a compensatory strategy often employed in the management of dysphagia in the PD population (Logemann et al., 2008). Even without the use of thickened fluids, discomfort when drinking fluids due to coughing or choking and reduced efficiency in drinking may result in a reduction in fluid intake and consequently lead to dehydration.

Malnutrition is an additional consequence that may relate to discomfort when eating and therefore, eating avoidance. Additionally, modified diets that are often put in place to alleviate discomfort and reduce choking risk, can impact on appetite and food enjoyment. Difficulties finding foods that can be safely eaten and are palatable is also a significant factor reported by people with PD (Leow, Huckabee, Anderson, & Beckert, 2010). Issues with mobility may impact on ability to prepare meals, and prolonged episodes of freezing may limit opportunities to eat. The increased movement due to PD symptoms such as dyskinesia, rigidity, disturbed sleep, and tremor, results in increased energy expenditure and a potential increased need for a higher daily caloric intake (Kistner, Lhommee, & Krack, 2014). As adequate nutrition is required to maintain muscle mass, malnutrition can result in further

physical decline. Recent studies investigating the prevalence of malnutrition in the community based PD population report approximately 15-20% of individuals with PD are malnourished or at risk of malnutrition (Sheard, Ash, Mellick, Silburn, & Kerr, 2013; Wang et al., 2010).

In addition to physical health consequences, dysphagia in PD can have a psychosocial impact. PD has been associated with a reduction in quality of life (Leow et al., 2010; Plowman-Prine et al., 2009), particularly when depression and clinical fluctuations are present or in more advanced stages of the disease (Slawek, Derejko, & Lass, 2005). Leow et al. (2010) used the Swallowing-related Quality of Life survey (SWAL-QOL) to investigate the impact of dysphagia related to PD on quality of life. The SWAL-QOL is a comprehensive patient-based dysphagia-specific questionnaire requiring ratings of 44 items within the ten domains (McHorney et al., 2000; McHorney et al., 2002). Those with dysphagia had poorer quality of life in the SWAL-QOL domains of mental health and social participation (Leow et al., 2010).

2.5.4 Clinical presentation of dysphagia in Parkinson's disease

A number of studies have reported on the presentation of oral pharyngeal dysphagia in PD. Some studies relied on clinically-based assessments, which lack objectivity, such as that used by Volonte, Porta, and Comi (2002). This study reports features of dysphagia in PD to include impaired mouth opening, palatal elevation, and lingual protrusion, and the presence of wet voice and/or cough after liquid intake, and infrequently after solids. More robust studies have employed instrumental assessments such as VEES (Suntrup et al., 2013), VFSS (Ali et al., 1996; Baijens et al., 2011; Hunter, Crameri, Austin, Woodward, & Hughes, 1997; Lin et al., 2012; Nagaya et al., 2000; Nagaya, Kachi, Yamada, & Igata, 1998; Stroudley & Walsh, 1991), electromagnetic mid-sagittal articulography (EMA) (Van Lieshout, Steele, & Lang, 2011), surface electromyography (sEMG) (Nagaya et al., 2000), and pharyngeal manometry (Ali et al., 1996) to assess the features of dysphagia in PD. A range of oral and pharyngeal dysphagic features has been associated with PD when subjective visual perceptual measures are used during instrumental assessment. These features are summarised in Table 2-1.

Table 2-1 - Oral and pharyngeal dysphagia features associated with PD through subjective instrumental assessment.

Feature	Assessment	Study
Anterior spillage	VFSS	(Stroudley & Walsh, 1991)
Oral residue	VFSS	(Ali et al., 1996; Nagaya et al., 2000)
Lingual tremor	VFSS	(Ali et al., 1996)
Tongue pumping	VFSS sEMG	(Ali et al., 1996; Nagaya et al., 2000)
Bradykinesia of the base of tongue	VEES	(Suntrup et al., 2013)
Abnormal tongue movements and reduced bolus control	VFSS	(Stroudley & Walsh, 1991)
Pre-swallow pooling/delayed pharyngeal swallow	VFSS VEES	(Ali et al., 1996; Hunter et al., 1997; Nagaya et al., 2000; Stroudley & Walsh, 1991; Suntrup et al., 2013)
Piecemeal deglutition	VFSS	(Ali et al., 1996; Nagaya et al., 2000)
Reduced posterior motion of the tongue base	VEES	(Suntrup et al., 2013)
Reduced laryngeal elevation	VEES	(Suntrup et al., 2013)
Vallecular residual	VFSS VEES	(Ali et al., 1996; Hunter et al., 1997; Nagaya et al., 2000; Suntrup et al., 2013)
Pyriform sinus residual	VFSS VEES	(Ali et al., 1996; Nagaya et al., 2000; Suntrup et al., 2013)
Coating of the posterior pharyngeal wall	VFSS VEES	(Ali et al., 1996; Suntrup et al., 2013)
Abnormal pharyngeal wall movement	VFSS	(Ali et al., 1996)
Abnormal pharyngeal motility	VFSS	(Stroudley & Walsh, 1991)

Penetration	VFSS VEES	(Hunter et al., 1997; Stroudley & Walsh, 1991; Suntrup et al., 2013)
Aspiration	VFSS	(Ali et al., 1996; Hunter et al., 1997; Nagaya et al., 2000; Nagaya et al., 1998; Stroudley & Walsh, 1991; Suntrup et al., 2013)

Features of dysphagia due to PD identified by more objective, quantifiable measurements are summarised in Table 2-2.

Table 2-2 - Oral and pharyngeal dysphagia features associated with PD through objective instrumental assessment

Feature	Assessment	Study
Prolonged premotor time	sEMG	(Nagaya et al., 2000)
Smaller tongue movements laterally	EMA	(Van Lieshout et al., 2011)
Longer oral transit times	VFSS	(Nagaya et al., 1998)
Slowed velopharyngeal closure	VFSS	(Baijens et al., 2011)
Longer pharyngeal transit times	VFSS	(Lin et al., 2012)
Delayed pharyngeal swallow	VFSS	(Lin et al., 2012)
Increased pressure in the hypopharynx	Pharyngeal manometry	(Ali et al., 1996)
Reduced variability of hypopharyngeal pressure in response to bolus size	Pharyngeal manometry	(Ali et al., 1996)
Incomplete UES opening	Pharyngeal manometry	(Ali et al., 1996)
Longer time taken for the UES to open in PD individuals who also aspirated	VFSS	(Nagaya et al., 1998)

A number of the swallowing features attributed to those with PD described in Table 2-1 and Table 2-2 were also evident in some of the control participants (Ali et al., 1996; Baijens et al., 2011) but a greater number of PD patients with perceived dysphagia displayed these features than PD patients without perceived dysphagia or the control participants. Instrumental assessments such as sEMG, EMA, and manometry are quantifiable as data regarding timing, muscle activation or pressure is provided. VFSS is open to subjective interpretation but

objective measurements and timing of bolus flow and anatomical movement can be applied. Reliability data was reported for both subjective and objective measures in two of the studies summarised in Table 2-1 and Table 2-2 (Baijens et al., 2011; Nagaya et al., 1998). VFSS is the only assessment for which reliability data is reported. The subjectively determined features of dysphagia are rated as either present or absent on VFSS without a judgement of degree or severity of this feature. Baijens et al. (2011) provide data that reflects stronger inter-rater reliability for objective rather than subjective VFSS assessment measures but intra-rater test-retest reliability is not improved by objective measures. Nagaya et al. (1998) reported high intra-rater reliability (ICC > 0.7) across all objective measures but inter-rater reliability, although good for both subjective and objective measures, is stronger for the subjective measures. This suggests that the measures chosen to assess some aspects of timing may involve anatomical features that are difficult to view, or standardized training in the definitions of each timing measure may be required. As there is no mention of blinding, it is also possible that bias played a role. Although Hunter et al. (1997) do not report reliability data, the quantitative measures used were more sensitive to changes in swallowing function than subjective measures.

Lin et al. (2012) retrospectively reviewed medical records and compared VFSSs of those participants who had a history of aspiration pneumonia to those who did not. Timing measures were used to track bolus flow through the oral and pharyngeal cavities. Longer swallowing times were found in those with aspiration pneumonia noted in their medical histories and this was more pronounced with thicker consistencies.

2.5.5 Swallowing efficiency in Parkinson's disease

Lin et al. (2012) also found reduced swallowing efficiency, in terms of speed in which a bolus moves through the oral and pharyngeal cavity, to be an important factor relating to development of aspiration pneumonia in patients with PD. This finding highlights the importance of clinical assessment of swallowing efficiency.

Miller et al. (2009) investigated efficiency of swallowing fluids in 137 individuals with PD. Participants were in an 'off' medication state and the 150 ml TWST was used. Swallowing rate was slower in over 80% of participants compared to the published norms provided by Hughes and Wiles (1996).

Kanna and Bhanu (2014) investigated performance of 100 patients with PD and 100 age- and gender-matched controls on a 150 ml timed water swallowing task. This task differed from that used by Hughes and Wiles (1996) because patients were instructed to swallow the water at their normal speed and timing commenced with the participant holding the water in their mouths. Swallowing speed (ml/s), swallowing volume (ml/swallow), and swallowing duration (s/swallow) were then calculated. A PD patient who coughed during this task was excluded from analysis indicating that patients with swallowing impairment were under represented. Kanna and Bhanu (2014) reported slower swallowing speed, smaller swallowing volume, and longer swallowing duration in the PD patients compared to controls. All of the differences in swallowing measures between these groups were reported to be statistically significant ($p < 0.05$). However, specific values are not reported and the statistical methods used in this study are unclear.

The TOMASS and TWST were used as baseline measures in a pilot study investigating a skill-based swallowing rehabilitation approach in PD by Athukorala et al. (2014) which has shown promising results for improving swallowing efficiency with a positive impact on quality of life. This within-subject design employed solid and fluid swallowing efficiency as outcome measures. Surface EMG with electrodes placed on the masseter muscle was used during the TOMASS to confirm reliability of visual assessment of masticatory cycles with a high level of agreement found between these two measures (ICC > 0.8). Treatment was found to result in improvements in the areas of time per swallow and volume per swallow with the TWST. Despite improvements in the TWST outcome measure and an observed trend on TOMASS measures, there was no improvement seen in the TOMASS performance. It is unclear if this is due to a lack of statistical power in this pilot study, reduced treatment effect on the oral phase of swallowing, the mild nature of PD severity among participants, or the sensitivity of the TOMASS for detecting change in oral phase swallowing in the PD population.

2.6 Aims and Hypotheses

2.6.1 Aims

1. To determine whether the TOMASS is a sensitive assessment tool for detecting a reduction in swallowing efficiency that may result from the presence of PD.

2. To determine whether the TOMASS is a sensitive assessment tool for detecting a reduction in swallowing efficiency that may result from increased severity of PD motor symptoms.
3. To determine whether there is a positive relationship between the TOMASS and the TWST as objective measures of swallowing efficiency in the PD population.

2.6.2 Research question 1

Is the TOMASS is a sensitive assessment tool for detecting reduced swallowing efficiency that may result from the presence of PD?

2.6.2.1 Hypothesis 1

Participants with PD will display reduced performance on the TOMASS compared to healthy age and gender matched controls as evidenced by:

1a) Increased time per-swallow with increased PD severity.

1b) Increased masticatory cycles per-swallow with increased PD severity.

1c) Increased swallows per-bite with increased PD severity.

2.6.2.2 Rationale

The TOMASS provides a quantifiable measure of efficiency of swallowing a solid bolus. Reduced swallowing efficiency has been found to be a result of dysphagia in PD (Lin et al., 2012; Miller et al., 2009; Umemoto et al., 2011). The TOMASS is likely to be more sensitive to impairment of oral phase swallowing than fluid swallowing tests and is able to assess mastication. A number of oral phase swallowing impairments have been associated with dysphagia in the PD population (Ali et al., 1996; Nagaya et al., 2000; Nagaya et al., 1998; Suntrup et al., 2013; Van Lieshout et al., 2011).

2.6.2.3 Significance

Prior to the TOMASS being widely adopted for clinical assessment, it needs to be established whether or not the TOMASS is sensitive to changes in swallowing resulting from neurological impairment.

2.6.3 Research question 2

Is the TOMASS is a sensitive assessment tool for detecting reduced swallowing efficiency that may result from increased severity of PD motor symptoms?

2.6.3.1 Hypothesis 2

Performance on the TOMASS will decline with increased PD severity as evidenced by:

1a) Increased time per-swallow with increased PD severity.

1b) Increased masticatory cycles per-swallow with increased PD severity.

1c) Increased swallows per-bite with increased PD severity.

2.6.3.2 Rationale

Dysphagia prevalence rates increase as disease severity increases (Kalf et al., 2012). Reduced oral phase swallowing efficiency has been found to correlate with PD severity (Umemoto et al., 2011).

2.6.3.3 Significance

Self-report regarding the presence of dysphagia has been found to be unreliable in the PD population (Ali et al., 1996; Kalf et al., 2012; Miller et al., 2009; Nagaya et al., 2000) and, therefore, reliable clinical screening of dysphagia in the PD population is required. Currently, severity of PD is assessed by self-report and clinical assessment. By assessing if the TOMASS is sensitive to changes in PD severity rather than just the presence or absence of PD, a better insight into the sensitivity of the TOMASS and it's relationship with dysphagia will be gained. Reduced swallowing efficiency has been found to be a result of dysphagia in PD (Lin et al., 2012; Miller et al., 2009; Umemoto et al., 2011). If the performance on the TOMASS is found to correlate with severity of PD this test may assist clinically in the prompt identification of dysphagia in PD and provide an additional clinical assessment to assist in determination of Parkinson's severity. Additionally, this test may be a useful research tool in studying dysphagia in PD and changes in symptoms.

2.6.4 Research question 3

Will participant's performance on the TOMASS correlate with performance on the TWST with performance on both tests decreasing as PD severity increases?

2.6.4.1 Hypothesis 3

Performance on the TOMASS will have a positive correlation with performance on the TWST.

2.6.4.2 Rationale

Dysphagia prevalence rates increase as disease severity increases (Kalf et al., 2012). Reduced oral phase swallowing efficiency has been found to correlate with PD severity (Umemoto et al., 2011). Comparison of performance on the TOMASS with a test that has already been validated in this population, The Timed Water Swallowing Test (TWST) may provide further insight in to the validity of the TOMASS

2.6.4.3 Significance

A greater understanding the differences and relationship between swallowing fluids and

swallowing solids in PD may contribute to a greater understanding of the nature of dysphagia in PD. There is some indication that swallowing efficiency for solids may be more impaired than for liquids in the PD population (Lin et al., 2012) however this has not been thoroughly investigated. Because significant improvements after a skill-based treatment were found in the TWST but not the TOMASS by Athukorala et al. (2014) the TWST may be more sensitive at measuring change in swallowing function than the TOMASS.

Chapter 3. Method

3.1 Participants

Participants were recruited through specialist PD services and were categorised into four groups of participants:

1) Twenty patients with mild-moderate PD.
2) Twenty patients with advanced PD.
3) Twenty healthy controls, age (±5 years) and gender matched to individuals in the mild-moderate PD group.
4) Twenty healthy controls, age (±5 years) and gender matched to individuals in the advanced PD group.

Participants with PD were required to have a firm diagnosis of PD as determined by a neurologist using the United Kingdom Brain Bank Criteria. Participants were excluded from the study if they presented with or had a history of any of the following:

- Medically diagnosed stroke or traumatic brain injury
- Neurological illness or muscular disease other than PD
- Head and/or neck injury/surgery with a potential impact on swallowing (including deep brain stimulation)
- Dementia to a degree where they would be unable to follow instructions or complete tasks required for the study
- Parkinsonism due to progressive supranuclear palsy, multiple system atrophy, or side effects of medications
- Deemed clinically unsafe to participate by the researcher based on information gained from the Eating Assessment Tool (EAT-10) questionnaire, medical records or clinical assessment.

A record of the number of participants deemed unsafe to participate due to choking or aspiration risk was kept. Participants were instructed to continue their medications as per usual and assessment was performed at a time of day that PD participants reported they were

'on' in terms of benefitting from the effects of their PD medications.

Additional data recorded for each participant included age, sex, medications and dose, time between last PD medication dose taken and commencement of assessment, and number of years post initial PD diagnosis. This information was acquired through a combination of participant self-report and medical history review. Signed consent to participate was acquired from all participants prior to their participation.

3.1.1 Assignment of Parkinson's disease severity rating

Participants with PD were assigned to one of the PD groups based on PD severity determined through administration of the MDS-UPDRS part III motor examination (Goetz et al., 2010) and assignment of a Hoehn and Yahr severity rating (Goetz et al., 2004). Participants with a Hoehn and Yahr rating of I to III were assigned to the mild-moderate PD group. Participants with a Hoehn and Yahr rating of IV or V were assigned to the advanced PD group. If a control participant matched a participant in age (±5 years) and gender for both PD groups they were assigned to both control groups.

3.1.2 Dysphagia survey

The EAT-10 questionnaire was chosen for use in this study as a dysphagia screening tool. This ten item, five point Likert scale design is quick and easy to complete with established criterion-based validity, and test-retest reliability. Normative data has been gained and a score of '3' is considered as abnormal and therefore indicative of dysphagia. Means and ranges for specific dysphagia diagnoses have also been provided (Belafsky et al., 2008) with PD contributing to the range of dysphagia aetiologies of the 235 individuals included in validation sample.

All participants were provided with the EAT-10 to independently complete once explained by the primary researcher. Some participants with PD required assistance to complete this questionnaire. When assistance was provided, care was taken to ensure that the individuals with PD rather than their carers directed responses.

3.2 Procedures

All experimental tasks were completed in one assessment session by the primary researcher. Prior to commencement of the assessment and at times throughout assessment, the researcher checked with the participants with PD to ensure they were still "on" or perceptually experiencing the benefits of their PD medications.

3.2.1 Timed water swallowing test

The protocol outlined by Hughes and Wiles (1996) was followed for the TWST with the procedure completed twice. A beaker was used to measure 150 ml of water, which was then transferred into a cup. Participants were instructed to drink this water "as quickly as is comfortably possible". The number of swallows, time taken and total volume swallowed was recorded.

Time taken was recorded with a stopwatch application on an iPhone™. Timing started from the moment the water first touched the participant's lower lip and stopped when the larynx came to rest after all water had been consumed. Indicators such as exhalation, phonation or mouth opening also assisted in assessing swallow completion. Watching the participant's throat either anteriorly or laterally and counting instances of observable thyroid elevation was employed to assess number of swallows.

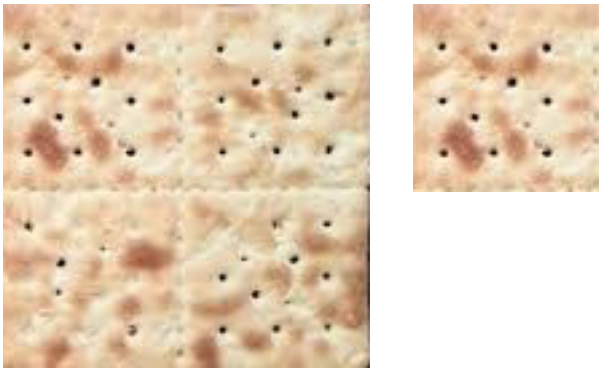
If participants were unable to drink the entire 150 ml of water due to postural limitations, swallowing discomfort, or coughing, the volume swallowed was calculated by measuring the remaining water left in the beaker and subtracting this from 150 ml. In the interest of timing accuracy, participants were asked to indicate they had finished by placing the cup down if they could not drink the entire 150 ml. If anterior spillage of the water was observed during completion of the test, a subjective judgement of the amount of water lost was made and subtracted from the 150 ml with the presence of anterior spillage noted. Both trials of this test were video-recorded using an iPad™ positioned to record in either an anterior or lateral view depending on which appeared to best provide an unobstructed view of the lips, jaw, and throat.

3.2.2 Test of Masticating and Swallowing Solids

Each participant completed two trials of the TOMASS. A sip of water was offered to

participants prior to each trial. Participants were presented with one quarter of an Arnotts Salada™ cracker and instructed, “when I say ‘go’, eat this as quickly as is comfortably possible and when you have finished say your name”. Time taken, number of swallows, number of masticatory cycles and number of bites were recorded for each trial.

Figure 1 - Full size and one-quarter segment of an Arnotts Salada™ cracker



Time taken was recorded using a stopwatch application on an iPhone™. Timing commenced as soon as the cracker touched the bottom lip or the teeth and was ceased when the participant said their name or produced an utterance or gesture to indicate that they had finished.

The number of swallows was assessed and tallied by watching the participant anteriorly or laterally and counting instances of observable thyroid elevation associated with swallowing. Auditory cues were also used to assess that swallowing had occurred where possible.

Number of masticatory cycles was assessed by counting the up then down movement of the jaw as one masticatory cycle. Each discrete bite of a segment of the whole cracker was also considered to be a masticatory cycle. As masticatory cycles occurred in rapid succession, the ‘lap’ function of a stopwatch was used to assist in tallying these events.

The number of bites was recorded by counting and tallying the number of discrete cracker segments placed in the mouth. For example, if the whole cracker was placed in the mouth at once this was counted as one bite. Both trials of this test were video-recorded using an iPad™ positioned to record in either an anterior or lateral view depending on which appeared to best provide an unobstructed view of the lips, jaw and throat.

The order in which the two swallowing tasks, TOMASS and TWST, were performed was

alternated from participant to participant to eliminate any bias that performance of one test might have on the other. This meant that half the participants in each group did the TOMASS before the TWST and half did the TWST before the TOMASS.

3.3 Analysis Plan

IBM Statistical Package for the Social Sciences Statistics Data Editor software was used for data analysis. TOMASS variables analysed included the raw data of total number of bites, masticatory cycles and swallows, and total time. From this data, further derived measures of masticatory cycles per bite, masticatory cycles per swallow, swallows per bite, time per bite, time per masticatory cycle, and time per swallow were calculated for analysis. TWST variables analysed were the raw data of number of swallows, total time and volume swallowed, derived measures of time per swallow, volume per swallow and volume per time. For all analyses of TOMASS and TWST measures, data from the second trial were used, as the first trial was considered a practice trial, with the exception of test-retest reliability where both trials were compared.

3.3.1 Reliability analyses

Reliability analyses were conducted on all TOMASS and TWST raw data variable with the exception of volume because this measurement was only performed by the primary researcher. Type A intraclass correlation coefficients using an absolute agreement definition and a two-way random effects model were used for reliability analyses. Intraclass correlation coefficient can be interpreted as follows: 0.0-0.2 poor agreement, 0.3-0.4 fair agreement, 0.5-0.6 moderate agreement, 0.7-0.8 strong agreement, and >0.8 almost perfect agreement (Portney & Watkins, 2000).

The 66 participants were randomized. The first 14 (approximately 20%) participants with video recordings displaying unobstructed second TOMASS and TWST trial images were reviewed. This selection resulted in inter- and intra-rater reliability analyses being conducted on five control participants, four mild-moderate PD participants, and five advanced PD participants.

3.3.1.1 Test-retest reliability

Test-retest reliability analyses were conducted on 65 of the 66 participants for the TOMASS. One participant's first TOMASS trial was omitted because of an interruption during the trial. Data from all 66 participants for the TWST were analysed.

3.3.1.2 Intra-rater reliability

The primary researcher rated video recordings twice with two days between each rating session. Intra-rater reliability analyses were performed on the 'real-time' rating and both video review ratings with three separate ratings per test variable analysed in total.

3.3.1.3 Inter-rater reliability

Two final year speech language therapy (SLT) students received a one hour training and practice session in rating the TWST and the TOMASS. Video recordings were reviewed and rated by the two SLT students separately. Inter-rater reliability analyses were conducted using the two SLT student ratings and the 'real-time' rating of the primary researcher (3 raters in total).

The inter-raters were blinded to the group assignment of the 14 participants rated and were asked to indicate whether or not they considered each participant had PD. A percentage of correct responses were then calculated to determine the level of blinding achieved.

3.3.2 Between-group analyses

Initial distribution analyses of TOMASS, TWST, and age data were completed. As the majority of the data were found to differ from a normal distribution based on findings from the Kolmogorov-Smirnov test and Levene's test, non-parametric tests were subsequently used for analyses. A Mann-Whitney test was the non-parametric test considered to be the most appropriate test for comparison of the level of difference in performance of each variable between groups and whether or not this difference was significant. Pearson's correlation coefficient *r* effect size was then calculated using the method outlined by Field (2011). In interpreting this effect size, 0.5 is the threshold for a large effect size, 0.3 for a medium effect, and 0.1 a small effect. However, for an effect to be clinically relevant in this population, an effect size larger than 0.5 would be indicated. Analyses between the PD groups of 20 and their matched groups of 20 controls, both PD groups, and a group formed of all 40 patients with PD and a group formed of all 26 control participants were performed.

A one-tailed Spearman's correlation coefficient was the non-parametric test used to further investigate the relationship between TOMASS and TWST performance and MDS-UPDRS PD severity score. The 40 PD participants were included in these analyses.

3.3.3 Between-test analyses

Spearman's correlation coefficient was the non-parametric test used to investigate the relationship between performance on the TWST and performance on the TOMASS. The relationship between TOMASS raw data measures and the total EAT-10 score was also analysed using Spearman's correlation coefficient. Initially all 66 participants were included in theses analyses. The control participants were removed from these analyses to eliminate bias and analyses were completed on the 40 participants with PD. Because positive relationships were hypothesised, one-tailed analyses were selected.

Chapter 4. Results

4.1 Reliability

Table 4-1 displays the intraclass correlation coefficients (ICC) for each of the TOMASS and TWST measures. Almost perfect agreement was seen across all measures of the TOMASS and TWST for test-retest and intra-rater reliability, indicating that participants were consistent in their performance of both tests from one trial to the next, that real-time intra-rater reliability between trial one and trial two was high, and video-recordings of these tests provided adequate clarity in order to complete ratings. Almost perfect inter-rater agreement was seen across both measures of the TWST and all TOMASS measures with the exception of swallows, which achieved moderate inter-rater agreement. There was no clear discrepancy between the rating of one rater compared to the other two raters in any of the measures, however, the real-time ratings had a general trend toward higher number of swallows. Only minor improvements were seen in the intraclass correlation coefficients for TOMASS swallows (0.76) when video ratings of all three raters were compared. This was not a trend observed across all measures.

Table 4-1 – Reliability data for TOMASS and TWST measures

	Test-retest reliability			**Intra-rater reliability**			**Inter-rater reliability**		
		95% Confidence Interval			95% Confidence Interval			95% Confidence Interval	
Test Measure	ICC Average Measures	Lower Bound	Upper Bound	ICC Average Measures	Lower Bound	Upper Bound	ICC Average Measures	Lower Bound	Upper Bound
TOMASS									
Bites	**.82***	.71	.89	**.98***	.95	.99	**.97***	.93	.99
Masticatory cycles	**.95***	.91	.97	**.99***	.96	.99	**.99***	.96	.99
Swallows	**.89***	.81	.93	**.84***	.61	.95	.67	.21	.88
Time	**.97***	.96	.98	**1.00***	1.00	1.00	**1.00***	.99	1.00
TWST									
Swallows	**.93***	.89	.96	**.97***	.92	.99	**.93***	.83	.98
Time	**.99***	.98	.99	**.99***	.99	1.00	**.99***	.99	.99

Type A intraclass correlation coefficients using an absolute agreement definition. Two-way random effects model **>0.8*** = almost perfect agreement.

It was noted that number of swallows was more difficult to assess in women than men and most difficult to assess in PD participants with dyskinesia. This subjective observation was reinforced by the finding that the greatest variance between raters was seen in a female PD participant with marked dyskinesia's causing additional movements of the neck and throat. The variance in number of TOMASS swallows assigned by each rater for the same participant ranged from 0 to 6 swallows with a median of 1 and a mean of 1.6. The impact of this participant on inter- and intra-rater reliability of TOMASS and TWST swallows was explored by assessing reliability if this participant's data was excluded. There was no change to TWST reliability, minimal improvement to TOMASS intra-rater reliability (.89). Inter-rater reliability, however, increased from moderate (.67) to strong (.80).

The presence or absence of PD was correctly determined in 78% and 82% of participants respectively by each blinded inter-rater. These figures indicate that blinding was limited.

4.2 Participants and group composition

A total of 74 participants consented to participate in this study. Data collection was completed on 68 of these participants with two of these participants later excluded from the study. A mild-moderate PD participant reported that he did not believe his PD medications were effective. Although his rationale related to ongoing symptoms caused by a coexisting disorder unrelated to PD, this participant's data were later excluded because they did not meet the inclusion criteria of a perceived feeling of benefitting from PD medications at the time of the assessment. A control participant was excluded due to ongoing dysphagic symptoms secondary to minor head and neck surgery that was reported after data collection.

Of the 44 patient participants who completed the MDS-UPDRS motor examination for potential inclusion, four PD participants were informed that they did not meet the PD severity criteria for the study. Two advanced PD participants were not able to complete or declined completion of the swallowing tasks with one declining to wear dentures and unable to bite the cracker to complete the experimental procedures and the other reporting that they avoid drinking due to continence issues and declined to drink an adequate amount to be included in data analysis.

One individual with advanced PD had a history of surgery for decompression of the facial nerve due to eyelid twitching; however, this surgery did not result in any impairment to the facial nerve, nor other swallowing related structures and therefore this participant was not excluded from the study. Twelve participants had documented dementia in their medical history (11 in the advanced PD group and one in the mild-moderate PD group).

Three individuals, whom, based on their observed mobility, would likely have met the advanced PD group criteria, were deemed unsafe to participate or declined to participate due to the severity of dysphagia. Two of these participants had undergone a recent VFSS and were prescribed puree diets as a result. The third individual declined participation due to a fear of choking.

In total, analyses were performed on the data collected from 66 individuals: 20 with mild-moderate PD; 20 with advanced PD and 26 healthy controls. Data from 14 of the 26 control participants were used across both control groups.

Both the mild-moderate and advanced PD groups were matched 1:1 for gender with their control groups. The overall PD group had a slightly higher (2%) representation of males than the overall control group.

There was no significant difference in participant age between the control for mild-moderate PD group (*Mdn* = 69.50) and the mild-moderate PD group (*Mdn* = 69.00), $U = 195.5$, $z = -.122$, $p = .45$, $r = -.019$. This was also true for the advanced PD group (*Mdn* = 74.50) and their control group (*Mdn* = 72.50), $U = 193.0$, $z = -.190$, $p = .43$, $r = -.030$ indicating that the control groups were successfully age matched to their respective PD groups. There was no significant difference in participant age when all control participants were grouped (*Mdn* = 70.00) and all PD participants grouped (*Mdn* = 72.00), $U = 518$, $z = -.026$, $p = .49$, $r = -.003$. Participant age between the mild-moderate PD group (*Mdn* = 69.00) and the advanced PD group (*Mdn* = 74.50) did, however, differ with the advanced PD group older than the mild-moderate PD group, $U = 119.5$, $z = -2.181$, $p = .014$, $r = -.345$.

Detailed figures and descriptive statistics for participants and group distribution are presented in the Appendix.

4.3 TOMASS and TWST between-group analysis

4.3.1 Parkinson's disease group vs control group

As displayed in Table 4-2, there were differences in TOMASS measures of total time, total number of swallows, and total number of masticatory cycles between participants with PD and healthy age matched controls. All TWST raw and derived measures reached significance between these groups. None of the TOMASS derived measures displayed between-group differences.

Table 4-2 - Comparison of TOMASS and TWST performance between all control participants and all PD participants.

Test Measure	Median control n=26	Median PD n=40	Mann-Whitney *U*	*p*-value (1-tailed)	*z*-score	*r* - effect size
TOMASS						
Bites	2.5	3.0	399	.053	-1.621	-.123
Masticatory cycles	55.0	69.5	301	**.002***	-2.875	-.354
Swallows	2.0	3.0	377	**.027***	-1.920	-.236
Time (s)	43.5	61.8	307	**.002***	-2.795	-.344
Masticatory cycles / bite	21.5	25.6	445	.166	-.978	-.120
Masticatory cycles / swallow	24.0	29.1	491	.354	-.381	-.047
Swallows / bite	1.0	1.0	492	.356	-.375	-.046
Time / bite (s)	9.4	7.0	437	.141	-1.083	-.133
Time / masticatory cycle (s)	.84	.83	518	.491	-.026	-.003
Time / swallow (s)	20.6	24.4	445	.165	-.984	-.121
TWST						
Swallows	6.0	10.0	244	**.000***	-3.911	-.481
Time (s)	11.2	25.9	399	**.000***	-3.622	-.446
Volume (ml)	150	150	223	**.042***	-2.053	-.253
Time / swallow (s)	1.5	2.1	346	**.011***	-2.283	-.281
Volume / swallow (ml)	25.0	15.0	221	**.000***	-3.935	-.484
Volume / time (ml/s)	13.5	5.8	240	**.000***	-3.674	-.452

*$p < .05$

4.3.2 Mild-Moderate PD group vs Mild-Moderate PD control group

As displayed in Table 4-3, there were only differences in TOMASS total time between the mild-moderate PD group and their age-matched control group. By contrast, there were differences in all TWST measures between these groups with the exception of volume.

Table 4-3 - Comparison of TOMASS and TWST performance between the control group for mild-moderate PD and the mild-moderate PD group.

Test Measure	Median control n = 20	Median mild-moderate PD n = 20	Mann-Whitney *U*	*p*-value (1-tailed)	*z*-score	r effect size
TOMASS						
Bites	2.5	3.0	175	.251	-.698	-.110
Masticatory cycles	56.5	68.5	143	.063	-1.543	.244
Swallows	2.0	2.0	177	.268	-.630	-.099
Time (s)	43.5	57.8	134	**.038***	-1.785	-.282
Masticatory cycles / bite	22.0	22.3	195	.449	-.135	-.021
Masticatory cycles / swallow	25.8	30.3	197	.476	-.068	-.011
Swallows / bite	1.0	1.0	196	.464	-.097	-.153
Time / bite (s)	8.8	6.8	180	.301	-.541	-.086
Time / masticatory cycle (s)	.79	.81	184	.337	-.433	-.068
Time / swallow (s)	20.8	27.2	173	.239	-.730	-.115
TWST						
Swallows	6.0	8.5	101	**.003***	-2.686	-.425
Time (s)	10.0	16.1	109	**.007***	-2.462	-.389
Volume (ml)	150	150	180	.244	-1.432	-.226
Time / swallow (s)	1.50	1.75	138	**.048***	-1.677	-.265
Volume / swallow (ml)	25.0	17.7	100	**.003***	-2.713	-.429
Volume / time (ml/s)	15.2	9.0	109	**.007***	-2.462	-.389

*****$p<.05$)

4.3.3 Advanced PD group vs Advanced PD control group

As displayed in Table 4-4, there were differences in all TOMASS raw data measures between participants with advanced PD and the healthy age-matched controls but none of the TOMASS derived measures. There were differences in all TWST measures between these groups with the exception of volume.

Table 4-4 - Comparison of TOMASS and TWST performance between the control group for Advanced PD and the Advanced PD group

Test Measure	Median control n = 20	Median advanced PD n = 20	Mann-Whitney *U*	*p*-value (1-tailed)	*z* - score	r effect size
TOMASS						
Bites	2.0	3.5	125	**.019***	-2.085	-.329
Masticatory cycles	54.0	88.0	94	**.002***	-2.868	-.453
Swallows	2.0	3.0	102	**.003***	-2.730	-.432
Time (s)	42.3	71.4	102	**.004***	-2.651	-.419
Masticatory cycles / bite	22.0	29.3	164	.169	-.974	-.154
Masticatory cycles / swallow	25.8	29.1	195	.455	-.122	-.019
Swallows / bite	1.0	1.0	176	.262	-.652	-.103
Time / bite (s)	9.7	7.0	147	.080	-1.420	-.225
Time / masticatory cycle (s)	.83	.84	196	.460	-.108	-.017
Time / swallow (s)	20.6	23.3	184	.339	-.433	-.068
TWST						
Swallows	6.5	11.0	59	**.000***	-3.818	-.604
Time (s)	11.2	26.5	64	**.000***	-3.679	-.582
Volume (ml)	150	150	160	.053	-2.079	-.329
Time / swallow (s)	1.5	2.5	114	**.010***	-2.326	-.368
Volume / swallow (ml)	23.2	13.6	59	**.000***	-3.831	-.606
Volume / time (ml/s)	13.4	5.5	61	**.000***	-3.760	-.594

**p*<.05

4.3.4 Mild-Moderate PD group vs Advanced PD group

As displayed in Table 4-5, there were no differences between the PD groups on any TOMASS or TWST measures. However, when comparing TOMASS and TWST measures across assigned MDS-UPDRS part III – motor examination ratings, positive correlations between increasing PD severity and increasing values on TOMASS masticatory cycles and time per masticatory cycle and TWST time, swallows, volume per swallow, and volume per time were found (Table 4-6).

Table 4-5 - Comparison of TOMASS and TWST performance between the mild-moderate PD group and the advanced PD group

Test Measure	Median mild-moderate PD n = 20	Median advanced PD n = 20	Mann-Whitney *U*	*p*-value (1-tailed)	*z*-score	r effect size
TOMASS						
Bites	3.0	3.5	158	.131	-1.142	-.181
Masticatory cycles	68.5	88.0	142	.061	-1.556	-.246
Swallows	2.0	3.0	156	.118	-1.197	-.189
Time (s)	57.8	71.4	158	.132	-1.136	-.179
Masticatory cycles / bite	22.3	29.3	176	.262	-.649	-.103
Masticatory cycles / swallow	30.3	29.1	190	.397	-.271	-.043
Swallows / bite	1.0	1.0	176	.265	-.642	-.102
Time / bite (s)	6.8	7.0	189	.392	-.284	-.045
Time / masticatory cycle (s)	.81	.84	195	.449	-.135	-.021
Time / swallow (s)	27.2	23.3	184	.339	-.433	-.068
TWST						
Swallows	8.5	11.0	139	.051	-1.643	-.260
Time (s)	16.1	26.5	147	.079	-1.434	-.227
Volume (ml)	150	150	179	.187	-.915	-.145
Time / swallow (s)	1.8	2.5	173	.239	-.730	-.115
Volume / swallow (ml)	17.7	13.6	142	.061	-1.559	-.246
Volume / time (ml/s)	9.0	5.5	148	.083	-1.407	-.222

*****$p<.05$

Table 4-6 - Relationship between TOMASS and TWST performance and MDS-UPDRS part III – motor examination PD severity ratings for the 40 PD participants

Test Measure	Spearman's Correlation Coefficient r_s (1-tailed)
TOMASS	
Bites	.16
Masticatory cycles	**.29***
Swallows	.10
Time (s)	.01
Masticatory cycles / bite	.08
Masticatory cycles / swallow	.10
Swallows / bite	-.02
Time / bite (s)	-.13
Time / masticatory cycle (s)	**-.33***
Time / swallow (s)	-.13
TWST	
Swallows	**.30***
Time (s)	**.27***
Volume (ml)	-.14
Time / swallow (s)	.13
Volume / swallow (ml)	**-.28***
Volume / time (ml/s)	**-.27***

*p<.05

Detailed figures relating to between group analyses are presented in the Appendix.

4.4 Between-test analysis

4.4.1 TWST and TOMASS

TOMASS time was related to TWST time, r_s = .41, p < .01. There was also a relationship between TOMASS swallows and TWST swallows, r_s = .49, p < .01. However, there was no significant relationship between the derived measures of TOMASS time per swallow and TWST time per swallow, r_s = .04, p = .41.

4.4.2 EAT-10 and TOMASS

Total EAT-10 score was related to TOMASS time, r_s = .41, p < .01 and swallows, r_s = .39, p

< .01. There was no significant relationship between total EAT-10 score and masticatory cycles, r_s = .22, p = .090, and bites r_s = .24, p = .069 when only the PD participants were included in the analyses.

Detailed figures relating to between test analyses are presented in the Appendix.

Chapter 5. Discussion

This study contributes to a body of evidence being developed on the sensitivity, validity, and clinical application of the TOMASS.

5.1.1 Reliability

The high reliability of TOMASS measures displayed in this study indicates that the TOMASS is indeed a quantifiable and objective measure of solid food swallowing. If the TOMASS is found to be a valid dysphagia assessment tool, its use would increase the reliability of the oral trial component of the CSE. There is some indication that inter-rater reliability of the TOMASS number of swallows variable might be reduced in neurogenic populations where the presence of dyskinesias may obstruct a clear view of the head and neck area during assessment. Battel, Koch, and Huckabee (2015) compared the swallowing efficiency of 23 individuals with PD, 23 individuals with multiple sclerosis, and 22 matched controls using the same TOMASS and 150 ml TWST procedures as the current study. The moderate inter-rater reliability for TOMASS number of swallows found in the current study is also reported by Battel et al. (2015) (ICC = .67). All other TOMASS and TWST variables displayed 'almost perfect agreement' (ICC >.90) (Battel et al., 2015). In contrast, 'almost perfect' inter-rater agreement on TOMASS number of swallows was observed by Athukorala et al. (2014) where all individuals in the patient group were reported to have mild-moderate PD. The differences in PD severity between these studies may account for reduced reliability for swallows in this study. The discrepancy in reliability of the number of swallows between the TOMASS and the TWST seen in this study could be explained by the presence of hyoid movement during mastication and the transfer cycle (Palmer et al., 1992). This occurs during ingestion of solid but not liquid boluses and could be misinterpreted as a swallow.

5.1.2 Presence of PD and swallowing efficiency

The increase in TOMASS total time, total number of swallows, and total number of masticatory cycles in the PD group compared to the control group indicates that the TOMASS, like the TWST, is sensitive enough to detect changes in swallowing function resulting from PD. The effect size of these TOMASS findings was, however, small. Battel et al. (2015) found that patients with PD had a greater total time, number of swallows and masticatory cycles on the TOMASS and also a greater total time and number of swallows on

the TWST when compared to healthy controls, reinforcing the findings of the current study. The severity of the patients with PD or multiple sclerosis was not reported by Battel et al. (2015) but no difference in TOMASS and TWST performance was observed between the PD and MS groups. The MS group differed from the group of healthy control participants on the TOMASS measures but not the TWST measures. Battel et al. (2015) proposed that reduced efficiency of swallowing solids may be a more sensitive measure of the presence of dysphagia than efficiency of swallowing fluids.

5.1.3 PD severity and swallowing efficiency

The more pronounced differences between the advanced PD group and control group, compared to the mild-moderate PD group and control group, indicates that the TOMASS is sensitive to increasing PD severity and appears to support the premise of Hypothesis 2. However, when the mild-moderate PD groups TOMASS performance was compared directly with the advanced PD groups TOMASS performance, there were no significant differences in all areas of the TOMASS. The number of masticatory cycles was the only TOMASS measure to show a positive relationship with PD severity and all correlations were low.

The low correlations and small effect sizes reported in this study for significant TOMASS variables indicate that relationships may not be clinically significant. However, it is possible that these findings were influenced by population bias. Participants who presented with severe dysphagia were excluded from this study due to safety concerns in completing the swallowing tasks and participants with no perceived dysphagia were included. Furthermore, only two participants presented with the most severe Hoehn and Yahr PD classification representing only 10% of the advanced PD group and 5% of the total PD group. A stronger relationship between TOMASS performance and PD severity may have been found if the participants were more representative of a clinical population.

It should also be noted that there was a wide range in performance of the TOMASS between individuals, with some individuals with PD being more efficient at completing these assessments than some of the individuals in the control group. This indicates that, like other dysphagia assessments, there may be issues regarding specificity of the TOMASS. However, further research into the validity of the TOMASS is required.

5.1.4 Relationship between TOMASS and TWST

There was a positive relationship between the TOMASS and TWST raw data measures of time and number of swallows indicating that the TOMASS is a solid food correlate to the 150 ml TWST presented by Hughes and Wiles (1996). The findings of this study indicate that the TOMASS and TWST have similar levels of sensitivity in response to PD severity although the TWST has a higher degree of significance and larger effect sizes on more measures, indicating that the TWST may be slightly more sensitive than the TOMASS as a measure of swallowing efficiency within the PD population.

5.1.5 Raw data vs derived measures

In the current study, although there were differences in the raw data measures for TOMASS between groups, differences were not observed in the derived measures. This was also noted by Battel et al. (2015). By contrast, many of the derived measures for the TWST displayed differences in both studies. A similar trend of the raw data showing differences reflected in more TOMASS raw data than derived measures was also seen in the TOMASS normative data study by Huckabee et al. (2015).

The same time per swallow could result from few swallows over a short time, or many swallows over a long time. Consequently, a shorter time per swallow is not always reflective of increased swallowing efficiency. The same logic applies to the derived measures of time per bite and time per masticatory cycle. The difference for the TWST compared to the TOMASS being that liquid ingestion requires minimal oral preparatory time with prompt swallowing onset on transfer into the pharynx, allowing for a more rapid and reflexive swallowing plan than solid ingestion (Palmer et al., 1992). The increased number of variables in the TOMASS allows for additional influences of one variable on another. For example, difficulty masticating could result in an increased total time and impact on the derived measure of time per swallow. The TWST derived measures are, therefore, more likely to reflect the raw data measures than the TOMASS derived measures would.

It was hypothesised that changes in TOMASS derived measures between groups would provide evidence for the sensitivity of the TOMASS. On reflection, changes in TOMASS raw data measures are more reflective of swallowing efficiency and therefore provide evidence for the sensitivity of the TOMASS. The treatment study completed by Athukorala et al.

(2014) only used the derived measures as TOMASS outcome measures, which could explain why changes were seen post-treatment in the TWST but not the TOMASS in that study.

5.2 Limitations of the study

5.2.1 Dentition

The design of this study did not control for impact of dentition on ability to complete the TOMASS. Data was not collected on the presence or condition of each participant's dentition. A study by Mishellany-Dutour, Renaud, Peyron, Rimek, and Woda (2008a), comparing the efficiency and success of mastication of solid foods between dentate young, dentate elderly, and elderly denture wearing adults suggests that dentures and age have a impact on efficiency in masticating solid foods. Those with dentures required the most masticatory cycles and were the least successful in masticating a bolus prior to a swallow. Warren et al. (2002) evaluated dental status and tooth loss in a longitudinal study of healthy aging adults and found that number of missing teeth rather than dental condition had in impact on quality of life measures including ease of chewing and ability to manage and swallow solid foods. The literature, therefore, suggests that dental status would impact on TOMASS completion and this would have been a relevant variable to include in the analyses and compare across groups.

The literature also suggests that individuals with PD may be at greater risk of having poor dentition than healthy age-matched participants. Nakayama, Washio, and Mori (2004) surveyed the oral health of 104 individuals and compared findings with a control group. Those with PD performed less oral hygiene care activities and had more difficulty chewing and more denture discomfort than the controls. The idea that the PD population may have poorer dentition which in turn may contribute to difficulty with mastication and therefore completion of the TOMASS was reinforced in a study completed by Pradeep et al. (2013). They completed comprehensive evaluations of the dentition of 45 individuals with PD and 46 age- and gender-matched controls. Participants were required to have a minimum of ten teeth and were excluded if they had a history of other health factors that may impact on oral health such as smoking or diabetes. The dental examiners were blinded to the objectives of the study. Findings included the presence of more dental decay with increasing severity of PD.

Even the mild PD group (Hoehn and Yahr rating of I) presented with a poorer dental condition than their matched controls.

Bakke, Larsen, Lautrup, and Karlsborg (2011) comprehensively evaluated the orofacial function and oral health of fifteen PD patients and compared their performance with age- and gender-matched controls. Objective assessment of masticatory performance and efficiency, oral stereognosis, jaw opening capacity, number of natural teeth and subjective evaluation of oral hygiene, dental condition and orofacial function was performed. Those with PD reported mastication to be more impaired and the presence of oral health problems more frequently than the controls did. The masticatory effectiveness was poorer in the PD group and appeared to become poorer with increasing PD severity. Masticatory efficiency, measured by total time taken to chew a standardised solid bolus from the first bite to first swallow, did not differ between groups. Jaw opening capacity was reduced in the PD group. The PD group also displayed poorer oral hygiene than the controls but there were no differences in number of natural teeth between groups.

Findings from these studies suggest that individuals with PD are at a higher risk of poor oral health, which may lead to fewer teeth and a greater need for dentures. However, dentition may have a stronger impact on efficiency of mastication than PD itself. This needs to be considered when interpreting the relationship between masticatory cycles and PD severity found in this study.

5.2.2 Measurement

Oral residual was noted to be present on completion of the TOMASS among participants in all groups. No attempt to quantify the amount of oral residual was made. Oral residual can indicate oral phase dysphagia. As oral residual was present in individuals across all groups it was felt that differences in interpretations of the instructions may have occurred. Some individuals indicated that they had “finished” after their first swallow had cleared the bulk of the bolus. Others made an attempt to clear every morsel of cracker from their mouth before indicating they had finished by stating their name. The TOMASS total time, although quantifiable, is impacted by participant’s subjective interpretation of the instructions. Any attempt to estimate the amount of oral residual for consideration in analyses would introduce a level of subjectivity that should be avoided in an otherwise quantifiable assessment. Unfortunately, anterior spillage during the TOMASS and TWST occurred with some

participants. Because volume swallowed is one of the TWST measures, the volume of spilt water had to be subjectively estimated by the examiner rather than objectively measured. Therefore, reducing the reliability of volume and derived measures relating to volume in this study.

5.2.3 Bias

An attempt was made to control for any bias concerning the presence of PD and TOMASS and TWST measures by blinding the two inter-raters to group assignment. However, it is acknowledged that in reviewing video-recordings it may be apparent which participants have PD. Although group assignment was not obvious for all participants, blinding was limited, and therefore bias was not well controlled for in this study. The high degree of inter-rater reliability across measures, however, does give an indication that bias is limited in measures which are largely objective.

The advanced and mild-moderate PD groups were not actively matched to each other for age and gender with the advanced PD group being older than the mild-moderate PD group. Increased age results in an increase in masticatory cycles and reduced masticatory effectiveness (Mishellany-Dutour, Renaud, Peyron, Rimek, & Woda, 2008b). Despite this, there were no significant differences in any TOMASS or TWST variables, so the age difference does not appear to bias outcomes. A regression analysis would better compare the relationship between performance on these swallowing tests and PD severity given that the groups are not matched. This type of analysis would also increase the power of the study. However, the bootstrapping procedure required for this analysis is beyond the scope of a Master's thesis.

The height and weight of participants was not recorded in this study. Height impacts on swallowing capacity in the TWST (Hughes & Wiles, 1996) and low body mass index has been positively correlated with increased dysphagia severity (Lam et al., 2007). Therefore, it would be relevant to include height and weight in the analyses to gain a better understanding of possible discrepancies between groups.

This study attempted to account for any effect that medication may have on completion of swallowing tests and assessment of PD severity. There is a large variation in the regularity and effectiveness of medication doses between patients. Subjective patient report was relied

upon to determine whether participants were benefitting from their medications at the time of the assessment and levodopa dose was not controlled for between the two PD groups. Inaccuracies in this subjective report may have impacted on the MDS-UPDRS assessment as medication has a known effect on motor skills (Hunter et al., 1997). Lim, Leow, Huckabee, Frampton, and Anderson (2008) found that PD medications did not impact on the TWST performance. Battel and Huckabee (2014b) investigated the influence of levodopa on performance of the TOMASS and TWST in 38 individuals with PD. There was no significant difference between individuals performance on these tests whether they were "on" or "off" medication but this study was low in statistical power. Hunter et al. (1997) did find differences in swallowing speed of semi-solids and solids "on" and "off" medications. Monte, da Silva-Junior, Braga-Neto, Nobre e Souza, and de Bruin (2005), however, found that patients with a higher levodopa dose had greater oral-pharyngeal swallowing efficiency.

5.2.4 Dysphagia screening

This study did not directly evaluate the relationship between performance on the TOMASS and the presence of oral or pharyngeal dysphagia. An instrumental assessment of swallowing such as VFSS is necessary to confirm the presence or absence of dysphagia and assess the validity of the TOMASS in screening for dysphagia. The positive relationship between TOMASS measures, TWST measures and EAT-10 score, however, does indicate that there is a relationship between reduced efficiency in the TOMASS and the presence of dysphagia.

The EAT-10 was chosen as part of a dysphagia screen for this study. Although patients with PD were used as part of the validation process for the EAT-10, it was not validated specifically for PD (Belafsky et al., 2008). It may have been more relevant to use the Swallowing Disturbance Questionnaire that was validated on 57 outpatients with PD by Manor et al. (2007) and found to have 80.5% sensitivity and 81.3% specificity for identifying the presence of dysphagia.

5.3 Future research directions

From the data collected in this study, further analyses could be completed to gain a greater understanding of the TOMASS in relation to PD and dysphagia. These analyses exceed the limits of this thesis document. The relationship between TOMASS and TWST measures and ratings of each individual EAT-10 question would provide further insights into the

relationship between reported difficulties specific to solids or liquids and actual performance ingesting these textures. Investigating the relationship between TOMASS measures and specific motor ratings on the MDS-UPDRS part III could provide further insight into connections between areas of motor impairment resulting from PD and swallowing impairment resulting from PD. Additionally, further statistical analyses would provide a stronger insight into PD severity as determined by the MDS-UPDRS and TOMASS and TWST measures. A linear regression analysis across MDS-UPDRS ratings on each of the swallowing test measures would provide more accurate insight into PD severity and TOMASS and TWST performance.

The presence of other documented indicators of dysphagia such as coughing, throat clearing, wet voice, and anterior spillage during or after oral intake, although noted during and post completion of the TOMASS and TWST, were not analysed for the purpose of this study. Wu et al. (2004) found that the sensitivity of the TWST increased when these measures were considered in clinical assessment. Further analyses of these more subjective dysphagia symptoms in combination with objective measures might reveal a stronger relationship between PD severity and swallowing impairment indicated through performance of the TOMASS. Anterior spillage and oral residual have been reported to be present in PD with anterior spillage found to be a strong indicator of dysphagia in PD (Lam et al., 2007). This study does not report the sensitivity or specificity of the TOMASS in identifying dysphagia in PD and further research in this area might be warranted.

This research compared performance on the TOMASS with other swallowing tests that have displayed an ability to indicate the presence of dysphagia such as the TWST and EAT-10 with positive relationships found. However, the current study did not directly investigate the relationship between TOMASS performance and the presence of dysphagia. Further research to investigate the validity of the TOMASS in clinically assessing the presence of dysphagia is warranted to determine further clinical application of the TOMASS within PD and other neurological populations. The use of instrumental swallowing assessment such as VFSS is recommended for this research.

Prior to future research on the TOMASS, considerations around administration of the TOMASS should be made. These considerations should include increasing the detail within the instructions for the TOMASS to reduce subjective interpretation, or changing the

guidelines to stop timing once a swallow has occurred to help to increase the objectivity of the TOMASS.

It is recommended that future research on the TOMASS:

- Control for dentition, particularly number of teeth, and the presence of dentures because this has been identified as a potential stronger influence on mastication time and effectiveness than neurological impairment.
- Use only TOMASS raw data in analyses, as the derived measures are less reflective of swallowing efficiency.
- Employ blinding to eliminate bias.
- Continue to use the TWST as a water-swallowing correlate.

5.4 Conclusions

The TOMASS shows merit as a swallowing screening tool and also as a treatment outcome measure provided that the raw data are used in the analyses. This study reinforces the finding by Battel et al. (2015) that the TOMASS is a sensitive assessment of reduced solid food swallowing efficiency caused by PD. The presence of PD rather than severity appears to have a stronger influence on reduced swallowing efficiency, however, PD severity does appear to play a role. Although differences in TOMASS variables between groups were found, the effect sizes are small, reducing the clinical applicability of these findings. However, the small effects seen could be explained by a population bias within this study because the participants were not representative of patients presenting clinically for swallowing assessment. The number of masticatory cycles appears to be the most sensitive measure in response to changes in PD severity but it is unclear what impact dentition has on this measure.

The TOMASS raw data measures were positively correlated with TWST measures and EAT-10 scores indicating that the TOMASS is a solid food correlate to the TWST as intended and there is a relationship between decreased efficiency in completing the TOMASS and the presence of dysphagia. Further research to validate the TOMASS is required before strong conclusions can be drawn on its clinical application.

References

Ali, G. N., Wallace, K. L., Schwartz, R., DeCarle, D. J., Zagami, A. S., & Cook, I. J. (1996). Mechanisms of oral-pharyngeal dysphagia in patients with Parkinson's disease. *Gastroenterology, 110*(2), 383-392.

Apperley, O., McIntosh, T., & Huckabee, M. L. (2015). Test of Masticating and Swallowing Solids (TOMASS): preliminary validation with oral anaesthesia. *Manuscript under review*.

Athukorala, R. P., Jones, R. D., Sella, O., & Huckabee, M. L. (2014). Skill training for swallowing rehabilitation in patients with Parkinson's disease. *Archives of Physical Medicine and Rehabilitation*. doi: 10.1016/j.apmr.2014.03.001

Baijens, L. W., Speyer, R., Passos, V. L., Pilz, W., Roodenburg, N., & Clave, P. (2011). Swallowing in Parkinson Patients versus Healthy Controls: Reliability of Measurements in Videofluoroscopy. *Gastroenterology Research and Practice, 2011*. doi: 10.1155/2011/380682

Bakke, M., Larsen, S. L., Lautrup, C., & Karlsborg, M. (2011). Orofacial function and oral health in patients with Parkinson's disease. *European Journal of Oral Sciences, 119*(1), 27-32.

Battel, I., & Huckabee, M. L. (2014a). *Comparison of oral phase swallowing efficiency for liquids and solids in Parkinson's disease, multiple sclerosis and healthy controls.* Paper presented at the The Dysphagia Research Society 22nd Annual Meeting Nashville, Tennessee.

Battel, I., & Huckabee, M. L. (2014b). *Oral phase swallowing efficiency in Parkinson's disease: on and off drug effects.* Paper presented at the The Dysphagia Research Society 22nd Annual Meeting Nashville, Tennessee.

Battel, I., Koch, I., & Huckabee, M. L. (2015). Clinical quantification of swallowing in patients with neurological disease. *Manuscript under review*.

Belafsky, P. C., Mouadeb, D. A., Rees, C. J., Pryor, J. C., Postma, G. N., Allen, J., & Leonard, R. J. (2008). Validity and reliability of the Eating Assessment Tool (EAT-10). *The Annals of Otology, Rhinology, and Laryngology, 117*(12), 919-924.

Berg, D., Postuma, R. B., Bloem, B., Chan, P., Dubois, B., Gasser, T., . . . Deuschl, G. (2014). Time to redefine PD? Introductory statement of the MDS Task Force on the definition of Parkinson's disease. *Movement Disorders, 00*(00), 1-9.

Bergstrom, L., Svensson, P., & Hartelius, L. (2013). Cervical auscultation as an adjunct to the clinical swallow examination: A comparison with fibre-optic endoscopic evaluation of swallowing. *International Journal of Speech-Language Pathology*. doi: 10.3109/17549507.2013.855259

Borr, C., Hielscher-Fastabend, M., & Lucking, A. (2007). Reliability and validity of cervical auscultation. *Dysphagia, 22*(3), 225-234.

Braak, H., Del Tredici, K., Rub, U., de Vos, R. A., Jansen Steur, E. N., & Braak, E. (2003). Staging of brain pathology related to sporadic Parkinson's disease. *Neurobiology of Aging, 24*(2), 197-211.

Braak, H., Ghebremedhin, E., Rub, U., Bratzke, H., & Del Tredici, K. (2004). Stages in the development of Parkinson's disease-related pathology. *Cell and Tissue Research, 318*(1), 121-134.

Caslake, R., Taylor, K., Scott, N., Gordon, J., Harris, C., Wilde, K., . . . Counsell, C. (2013). Age-, gender-, and socioeconomic status-specific incidence of Parkinson's disease and parkinsonism in northeast Scotland: the PINE study. *Parkinsonism & Related Disorders, 19*(5), 515-521.

Cassiani, R. A., Santos, C. M., Parreira, L. C., & Dantas, R. O. (2011). The relationship between the oral and pharyngeal phases of swallowing. *Clinics (Sao Paulo), 66*(8), 1385-1388.

Coelho, M., Marti, M. J., Tolosa, E., Ferreira, J. J., Valldeoriola, F., Rosa, M., & Sampaio, C. (2010). Late-stage Parkinson's disease: the Barcelona and Lisbon cohort. *Journal of Neurology, 257*, 1524-1532.

Collins, M. J., & Bakheit, A. M. (1997). Does pulse oximetry reliably detect aspiration in dysphagic stroke patients? *Stroke, 28*(9), 1773-1775.

Colodny, N. (2001). Effects of age, gender, disease, and multisystem involvement on oxygen saturation levels in dysphagic persons. *Dysphagia, 16*(1), 48-57.

DePippo, K. L., Holas, M. A., & Reding, M. J. (1992). Validation of the 3-oz water swallow test for aspiration following stroke. *Archives of Neurology, 49*(12), 1259-1261.

Fernandez, H. H., & Lapane, K. L. (2002). Predictors of mortality among nursing home residents with a diagnosis of Parkinson's disease. *Medical Science Monitor, 8*(4), CR241-246.

Field, A. (2011) *Discovering Statistics Using SPSS* (pp. 550). London: Sage Publications Inc.

Goetz, C. G., Poewe, W., Rascol, O., Sampaio, C., Stebbins, G. T., Counsell, C., . . . Seidl, L. (2004). Movement Disorder Society Task Force report on the Hoehn and Yahr staging scale: status and recommendations. *Movement Disorders 19*(9), 1020-1028.

Goetz, C. G., Stebbins, G. T., Chmura, T. A., Fahn, S., Poewe, W., & Tanner, C. M. (2010). Teaching program for the Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale: (MDS-UPDRS). *Movement Disorders 25*(9), 1190-1194.

Hori, K., Ono, T., & Nokubi, T. (2006). Coordination of tongue pressure and jaw movement in mastication. *Journal of Dental Research, 85*(2), 187-191.

Huckabee, M. L., McIntosh, T., & Apperley, O. (2014). *Quantitative assesment of oral phase efficiency: TOMASS norms and preliminary validation.* Paper presented at the Dysphagia Research Society 22nd Annual Meeting, Nashville, Tennessee.

Huckabee, M. L., McIntosh, T., Fuller, L., & Curry, M. (2015). Normative data and measures of inter-rater and test-retest reliability for the Test of Masticating and Swallowing Solids (TOMASS). *Manuscript under review*.

Hughes, A. J., Daniel, S. E., Kilford, L., & Lees, A. J. (1992). Accuracy of clinical diagnosis of idiopathic Parkinson's disease: a clinico-pathological study of 100 cases. *Journal of Neurology, Neurosurgery, and Psychiatry, 55*(3), 181-184.

Hughes, T. A., & Wiles, C. M. (1996). Clinical measurement of swallowing in health and in neurogenic dysphagia. *QJM, 89*(2), 109-116.

Hunter, P. C., Crameri, J., Austin, S., Woodward, M. C., & Hughes, A. J. (1997). Response of parkinsonian swallowing dysfunction to dopaminergic stimulation. *Journal of Neurology, Neurosurgery, and Psychiatry, 63*(5), 579-583.

Jean, A. (2001). Brain stem control of swallowing: neuronal network and cellular mechanisms. *Physiological Reviews, 81*(2), 929-969.

Kalf, J. G., Borm, G. F., de Swart, B. J., Bloem, B. R., Zwarts, M. J., & Munneke, M. (2011). Reproducibility and validity of patient-rated assessment of speech, swallowing, and saliva control in Parkinson's disease. *Archives of Physical Medicine and Rehabilitation, 92*(7), 1152-1158.

Kalf, J. G., de Swart, B. J., Bloem, B. R., & Munneke, M. (2012). Prevalence of oropharyngeal dysphagia in Parkinson's disease: a meta-analysis. *Parkinsonism & Related Disorders, 18*(4), 311-315.

Kanna, S. V., & Bhanu, K. (2014). A simple bedside test to assess the swallowing dysfunction in Parkinson's disease. *Annals of Indian Academy of Neurology, 17*(1), 62-65.

Kistner, A., Lhommee, E., & Krack, P. (2014). Mechanisms of body weight fluctuations in Parkinson's disease. *Frontiers in Neurology, 5*, 84.

Lam, K., Lam, F. K., Lau, K. K., Chan, Y. K., Kan, E. Y., Woo, J., . . . Ko, A. (2007). Simple clinical tests may predict severe oropharyngeal dysphagia in Parkinson's disease. *Movement Disorders, 22*(5), 640-644.

Langmore, S. E., Terpenning, M. S., Schork, A., Chen, Y., Murray, J. T., Lopatin, D., & Loesche, W. J. (1998). Predictors of aspiration pneumonia: how important is dysphagia? *Dysphagia, 13*(2), 69-81.

Leder, S. B., Suiter, D. M., & Green, B. G. (2011). Silent aspiration risk is volume-dependent. *Dysphagia, 26*(3), 304-309.

Leow, L. P., Huckabee, M. L., Anderson, T., & Beckert, L. (2010). The impact of dysphagia on quality of life in ageing and Parkinson's disease as measured by the swallowing quality of life (SWAL-QOL) questionnaire. *Dysphagia, 25*(3), 216-220.

Leslie, P., Drinnan, M. J., Finn, P., Ford, G. A., & Wilson, J. A. (2004). Reliability and validity of cervical auscultation: a controlled comparison using videofluoroscopy. *Dysphagia, 19*(4), 231-240.

Leslie, P., Drinnan, M. J., Zammit-Maempel, I., Coyle, J. L., Ford, G. A., & Wilson, J. A. (2007). Cervical auscultation synchronized with images from endoscopy swallow evaluations. *Dysphagia, 22*(4), 290-298.

Lim, A., Leow, L., Huckabee, M. L., Frampton, C., & Anderson, T. (2008). A pilot study of respiration and swallowing integration in Parkinson's disease: "on" and "off" levodopa. *Dysphagia, 23*(1), 76-81.

Lim, S. H., Lieu, P. K., Phua, S. Y., Seshadri, R., Venketasubramanian, N., Lee, S. H., & Choo, P. W. (2001). Accuracy of bedside clinical methods compared with fiberoptic endoscopic examination of swallowing (FEES) in determining the risk of aspiration in acute stroke patients. *Dysphagia, 16*(1), 1-6.

Lin, C. W., Chang, Y. C., Chen, W. S., Chang, K., Chang, H. Y., & Wang, T. G. (2012). Prolonged swallowing time in dysphagic Parkinsonism patients with aspiration pneumonia. *Archives of Physical Medicine and Rehabilitation, 93*(11), 2080-2084.

Logemann, J. A., Gensler, G., Robbins, J., Lindblad, A. S., Brandt, D., Hind, J. A., . . . Miller Gardner, P. J. (2008). A randomized study of three interventions for aspiration of thin

liquids in patients with dementia or Parkinson's disease. *Journal of Speech, Language, and Hearing Research, 51*(1), 173-183.

Manor, Y., Giladi, N., Cohen, A., Fliss, D. M., & Cohen, J. T. (2007). Validation of a swallowing disturbance questionnaire for detecting dysphagia in patients with Parkinson's disease. *Movement Disorders, 22*(13), 1917-1921.

McCullough, G. H., Wertz, R. T., Rosenbek, J. C., Mills, R. H., Ross, K. B., & Ashford, J. R. (2000). Inter- and intrajudge reliability of a clinical examination of swallowing in adults. *Dysphagia, 15*(2), 58-67.

McHorney, C. A., Bricker, D. E., Kramer, A. E., Rosenbek, J. C., Robbins, J., Chignell, K. A., . . . Clarke, C. (2000). The SWAL-QOL outcomes tool for oropharyngeal dysphagia in adults: I. Conceptual foundation and item development. *Dysphagia, 15*(3), 115-121.

McHorney, C. A., Robbins, J., Lomax, K., Rosenbek, J. C., Chignell, K., Kramer, A. E., & Bricker, D. E. (2002). The SWAL-QOL and SWAL-CARE outcomes tool for oropharyngeal dysphagia in adults: III. Documentation of reliability and validity. *Dysphagia, 17*(2), 97-114.

Miles, A., & Huckabee, M. L. (2013). Intra- and inter-rater reliability for judgement of cough following citric acid inhalation. *International Journal of Speech-Language Pathology, 15*(2), 209-215.

Miller, N., Allcock, L., Hildreth, A. J., Jones, D., Noble, E., & Burn, D. J. (2009). Swallowing problems in Parkinson disease: frequency and clinical correlates. *Journal of Neurology, Neurosurgery, and Psychiatry, 80*(9), 1047-1049.

Mishellany-Dutour, A., Renaud, J., Peyron, M. A., Rimek, F., & Woda, A. (2008b). Is the goal of mastication reached in young dentates, aged dentates and aged denture wearers? *The British Journal of Nutrition, 99*(1), 121-128.

Monte, F. S., da Silva-Junior, F. P., Braga-Neto, P., Nobre e Souza, M. A., & de Bruin, V. M. (2005). Swallowing abnormalities and dyskinesia in Parkinson's disease. *Movement Disorders 20*(4), 457-462.

Mu, L., Sobotka, S., Chen, J., Su, H., Sanders, I., Adler, C. H., . . . Beach, T. G. (2013). Alpha-synuclein pathology and axonal degeneration of the peripheral motor nerves innervating pharyngeal muscles in Parkinson disease. *Journal of Neuropathology and Experimental Neurology, 72*(2), 119-129.

Nagaya, M., Kachi, T., & Yamada, T. (2000). Effect of swallowing training on swallowing disorders in Parkinson's disease. *Scandinavian Journal of Rehabilitation Medicine, 32*, 11 - 15.

Nagaya, M., Kachi, T., Yamada, T., & Igata, A. (1998). Videofluorographic study of swallowing in Parkinson's disease. *Dysphagia, 13*(2), 95-100.

Nakayama, Y., Washio, M., & Mori, M. (2004). Oral health conditions in patients with Parkinson's disease. *Journal of Epidemiology 14*(5), 143-150.

Nathadwarawala, K. M., Nicklin, J., & Wiles, C. M. (1992). A timed test of swallowing capacity for neurological patients. *Journal of Neurology, Neurosurgery, and Psychiatry, 55*(9), 822-825.

Palmer, J. B., Rudin, N. J., Lara, G., & Crompton, A. W. (1992). Coordination of mastication and swallowing. *Dysphagia, 7*(4), 187-200.

Plowman-Prine, E. K., Sapienza, C. M., Okun, M. S., Pollock, S. L., Jacobson, C., Wu, S. S., & Rosenbek, J. C. (2009). The relationship between quality of life and swallowing in Parkinson's disease. *Movement Disorders 24*(9), 1352-1358.

Portney, L. G., & Watkins, M. P. (2000). Foundations of Clinical Research - Applications to Practice (pp. 560- 567). New Jersey: Prentice Hall Inc.

Pradeep, A. R., Singh, S. P., Martande, S. S., Raju, A. P., Rustagi, T., Suke, D. K., & Naik, S. B. (2013). Clinical evaluation of the periodontal health condition and oral health awareness in Parkinson's disease patients. *Gerodontology.* doi: 10.1111/ger.12055

Ramsey, D. J., Smithard, D. G., & Kalra, L. (2006). Can pulse oximetry or a bedside swallowing assessment be used to detect aspiration after stroke? *Stroke, 37*(12), 2984-2988.

Robbins, J., Gensler, G., Hind, J., Logemann, J. A., Lindblad, A. S., Brandt, D., . . . Miller Gardner, P. J. (2008). Comparison of 2 interventions for liquid aspiration on pneumonia incidence: a randomized trial. *Annals of Internal Medicine, 148*(7), 509-518.

Sheard, J. M., Ash, S., Mellick, G. D., Silburn, P. A., & Kerr, G. K. (2013). Malnutrition in a sample of community-dwelling people with Parkinson's disease. *PLoS One, 8*(1), e53290.

Slawek, J., Derejko, M., & Lass, P. (2005). Factors affecting the quality of life of patients with idiopathic Parkinson's disease--a cross-sectional study in an outpatient clinic attendees. *Parkinsonism & Related Disorders, 11*(7), 465-468.

Snow, B., & Macdonald, L. (2013). *Parkinson's: A Guide for the Newly Diagnosed*: Parkinson's New Zealand.

Spadotto, A. A., Gatto, A. R., Cola, P. C., Silva, R. G., Schelp, A. O., Domenis, D. R., & Dantas, R. O. (2012). Components of the acoustic swallowing signal: preliminary study. *Jornal da Sociedade Brasileira de Fonoaudiologia, 24*(3), 218-222.

Splaingard, M. L., Hutchins, B., Sulton, L. D., & Chaudhuri, G. (1988). Aspiration in rehabilitation patients: videofluoroscopy vs bedside clinical assessment. *Archives of Physical Medicine and Rehabilitation, 69*(8), 637-640.

Stroud, A. E., Lawrie, B. W., & Wiles, C. M. (2002). Inter- and intra-rater reliability of cervical auscultation to detect aspiration in patients with dysphagia. *Clinical Rehabilitation, 16*(6), 640-645.

Stroudley, J., & Walsh, M. (1991). Radiological assessment of dysphagia in Parkinson's disease. *The British Journal of Radiology, 64*(766), 890-893.

Suiter, D. M., & Leder, S. B. (2008). Clinical utility of the 3-ounce water swallow test. *Dysphagia, 23*(3), 244-250.

Suntrup, S., Teismann, I., Bejer, J., Suttrup, I., Winkels, M., Mehler, D., . . . Warnecke, T. (2013). Evidence for adaptive cortical changes in swallowing in Parkinson's disease. *Brain, 136*(Pt 3), 726-738.

Twelves, D., Perkins, K. S., & Counsell, C. (2003). Systematic review of incidence studies of Parkinson's disease. *Movement Disorders, 18*(1), 19-31.

Umemoto, G., Tsuboi, Y., Kitashima, A., Furuya, H., & Kikuta, T. (2011). Impaired food transportation in Parkinson's disease related to lingual bradykinesia. *Dysphagia, 26*(3), 250-255.

Van Lieshout, P. H. H. M., Steele, C. M., & Lang, A. E. (2011). Tongue control for swallowing in Parkinson's disease effects of age, rate, and stimulus consistency. *Movement Disorders, 26*(9), 1725-1732.

Volonte, M. A., Porta, M., & Comi, G. (2002). Clinical assessment of dysphagia in early phases of Parkinson's disease. *Neurological Sciences, 23 Suppl 2*, S121-122.

Walker, R. W., Dunn, J. R., & Gray, W. K. (2011). Self-reported dysphagia and its correlates within a prevalent population of people with Parkinson's disease. *Dysphagia, 26*(1), 92-96.

Wang, G., Wan, Y., Cheng, Q., Xiao, Q., Wang, Y., Zhang, J., . . . Chen, S. D. (2010). Malnutrition and associated factors in Chinese patients with Parkinson's disease:

Results from a pilot investigation. *Parkinsonism and Related Disorders, 16*(2), 119-123.

Wang, T. G., Chang, Y. C., Chen, S. Y., & Hsiao, T. Y. (2005). Pulse oximetry does not reliably detect aspiration on videofluoroscopic swallowing study. *Archives of Physical Medicine and Rehabilitation, 86*(4), 730-734.

Warms, T., & Richards, J. (2000). "Wet Voice" as a predictor of penetration and aspiration in oropharyngeal dysphagia. *Dysphagia, 15*(2), 84-88.

Warren, J. J., Watkins, C. A., Cowen, H. J., Hand, J. S., Levy, S. M., & Kuthy, R. A. (2002). Tooth loss in the very old: 13-15-year incidence among elderly Iowans. *Community Dentistry and Oral Epidemiology, 30*(1), 29-37.

Wu, M. C., Chang, Y. C., Wang, T. G., & Lin, L. C. (2004). Evaluating swallowing dysfunction using a 100-ml water swallowing test. *Dysphagia, 19*(1), 43-47.

Zenner, P. M., Losinski, D. S., & Mills, R. H. (1995). Using cervical auscultation in the clinical dysphagia examination in long-term care. *Dysphagia, 10*(1), 27-31.

Chapter 6. Appendix

Table 6-1 – Descriptive statistics for participant age and sex for each group

Group	Sex of participant				Age of participant in years			
	Male		Female		mean	median	Standard deviation	Range
	N	%	N	%				
All control participants (n = 26)	19	73	7	27	70	70	9.86	46-85
All PD participants (n = 40)	30	75	10	25	70.15	72.00	8.52	48-86
Control for mild-moderate PD (n = 20)	14	70	6	30	67.40	69.50	9.31	46-80
Mild-moderate PD (n = 20)	14	70	6	30	66.75	69.00	9.37	48-79
Control for advanced PD (n = 20)	16	80	4	20	73.30	72.50	6.67	62-85
Advanced PD (n = 20)	16	80	4	20	73.55	74.50	6.07	62-86

Figure 6-1 - Bar graph representing the mean age of participants between the PD groups and their respective control groups.

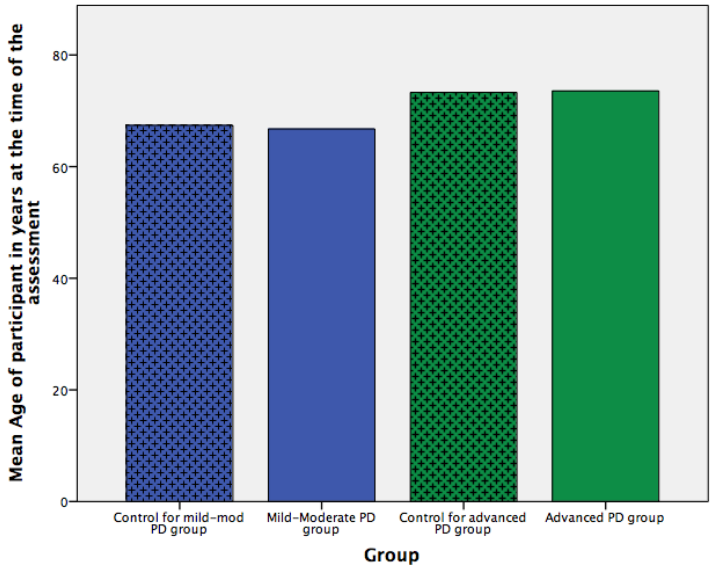


Table 6-2 - Descriptive statistics for years since PD diagnosis

	No. of years since formal PD diagnosis			
Group	Range	Mean	Median	Standard deviation
Mild-moderate PD (N = 20)	2 - 20	8.40	6.50	5.605
Advanced PD (N = 19)	5 - 35	16.47	15.00	8.161

Figure 6-2 - Box and whisker plot representing range and median MDS-UPDRS scores of PD groups

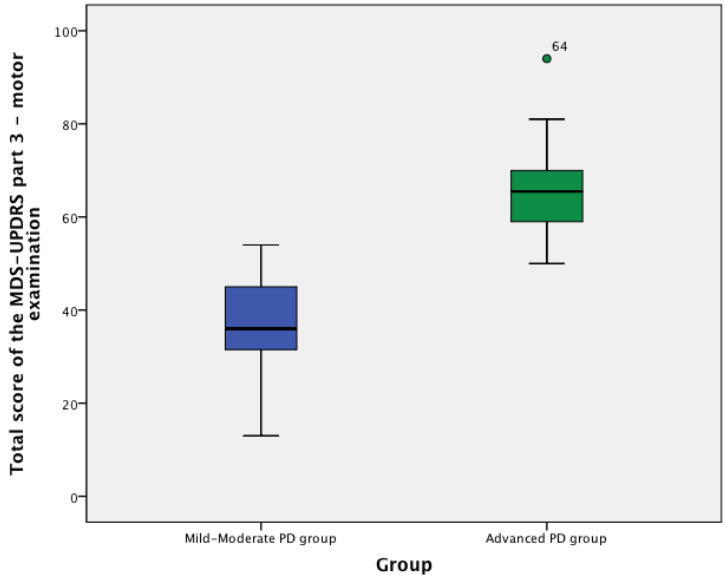


Table 6-3 – Descriptive statistics comparing Hoehn and Yahr and MDS-UPDRS scores across groups

	Hoehn and Yahr					**MDS-UPDRS score**			
Group (N = 20)	Score	Frequency	Percentage	Mean	Standard deviation	Range	Mean	Median	Standard deviation
Mild-moderate PD	2 2.5 3	11 5 4	55 25 20	2.325	.406	13 - 54	36.80	36.00	11.40
Advanced PD	4 5	18 2	90 10	4.05	.394	50 - 94	66.20	65.50	10.90

Table 6-4 – Descriptive statistics comparing EAT-10 scores between groups

	EAT-10 score			
Group (N = 20)	Range	Mean	Standard deviation	Percentage of scores ≤ 3
Control for mild-moderate PD	0 - 4	0.60	1.14	95
Mild-moderate PD	0 - 21	4.80	5.25	45
Control for advanced PD	0 - 4	0.60	1.14	95
Advanced PD	0 - 22	6.75	5.79	25

Scores higher than three indicate the presence of dysphagia (Belafsky et al., 2008).

Figure 6-3 - Box and whisker plot representing the median and range of EAT-10 scores between groups

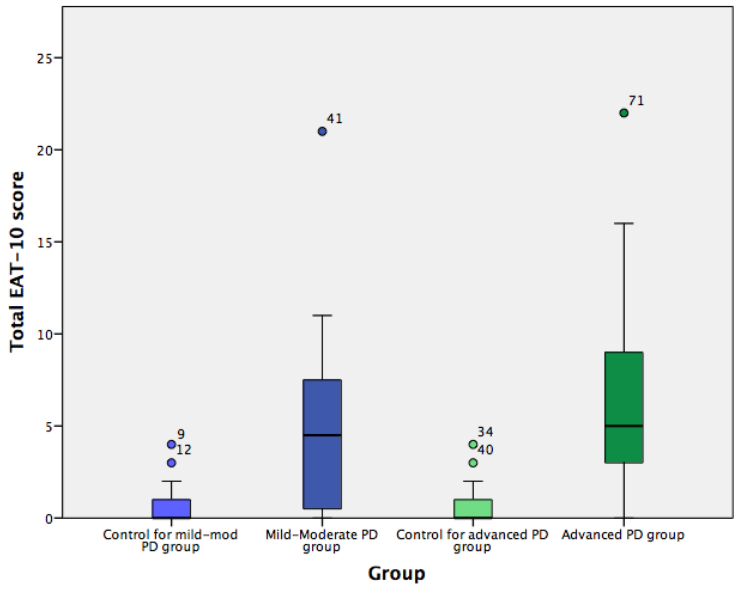


Figure 6-4 - Bar graphs representing group means for each TOMASS raw data variable

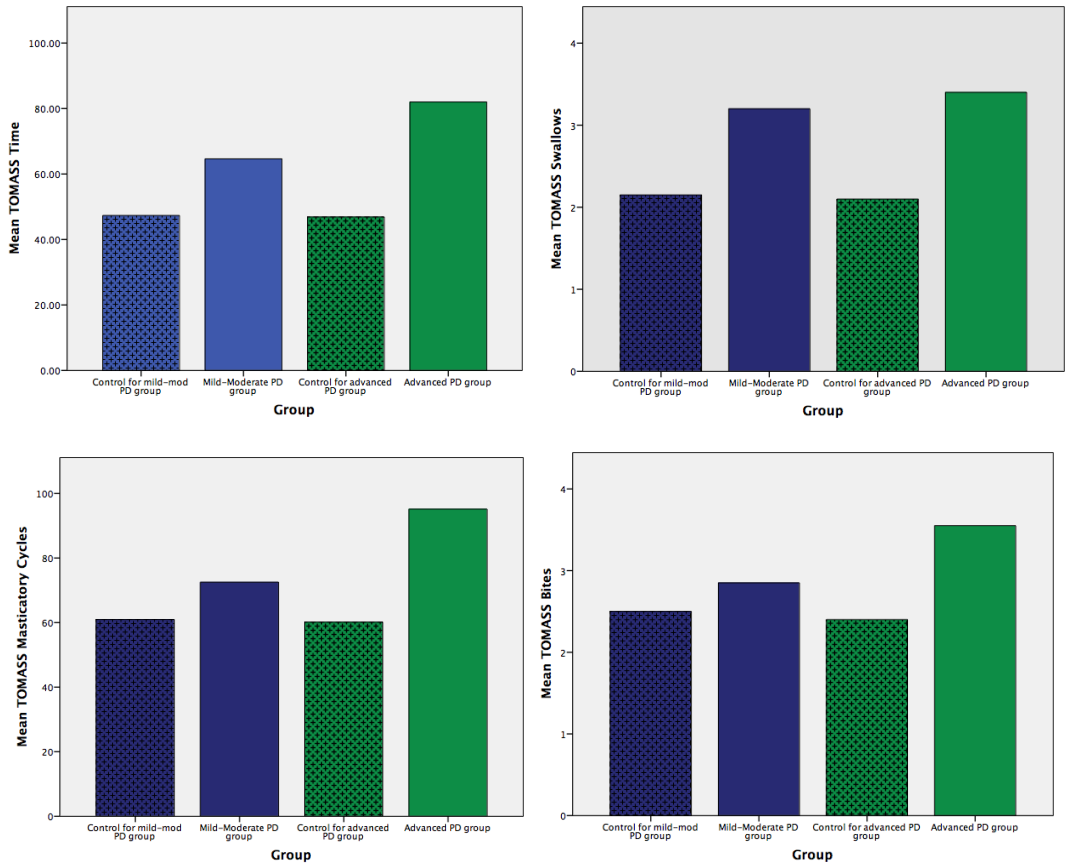


Figure 6-5 - Box and whisker plot representing distribution of time taken in seconds for the TOMASS across groups

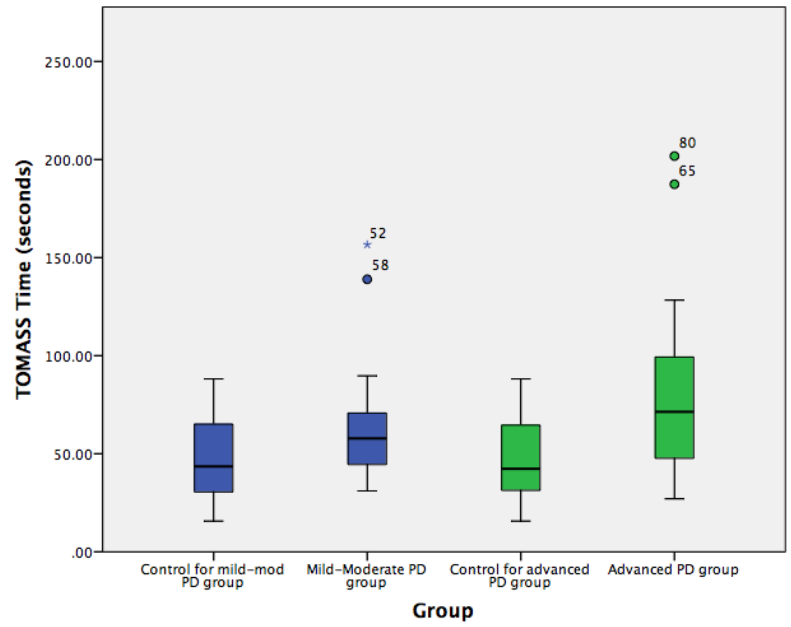


Figure 6-6 **Box and whisker plot representing distribution of number of swallows for the TOMASS across groups**

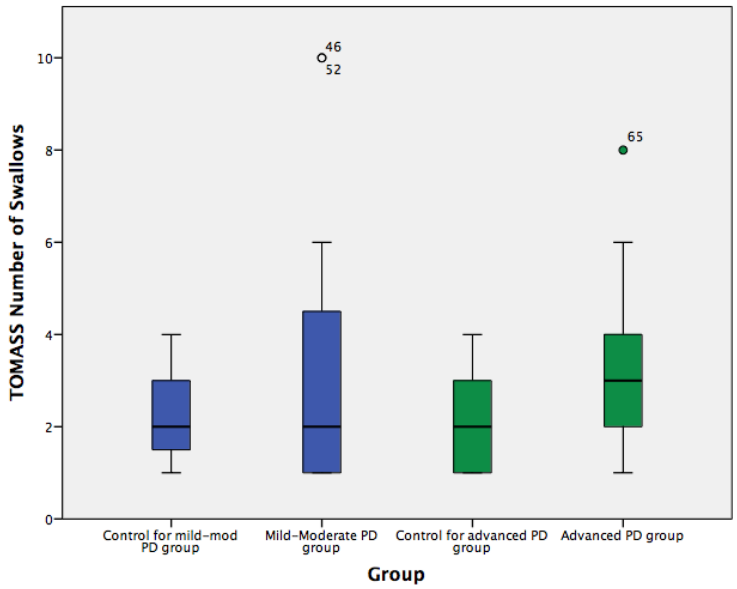


Figure 6-7 - Box and whisker plot representing distribution of Number of Masticatory Cycles for the TOMASS across groups

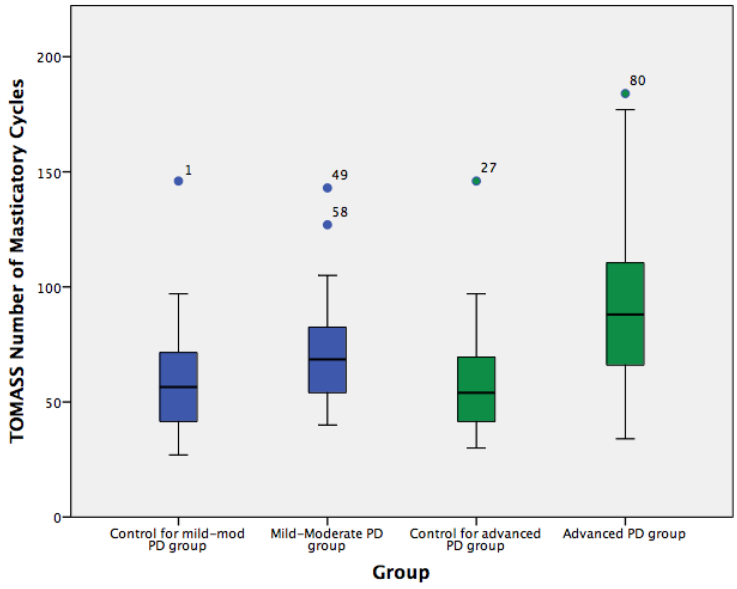


Figure 6-8 - Box and whisker plot representing distribution of Number of Bites for the TOMASS across groups

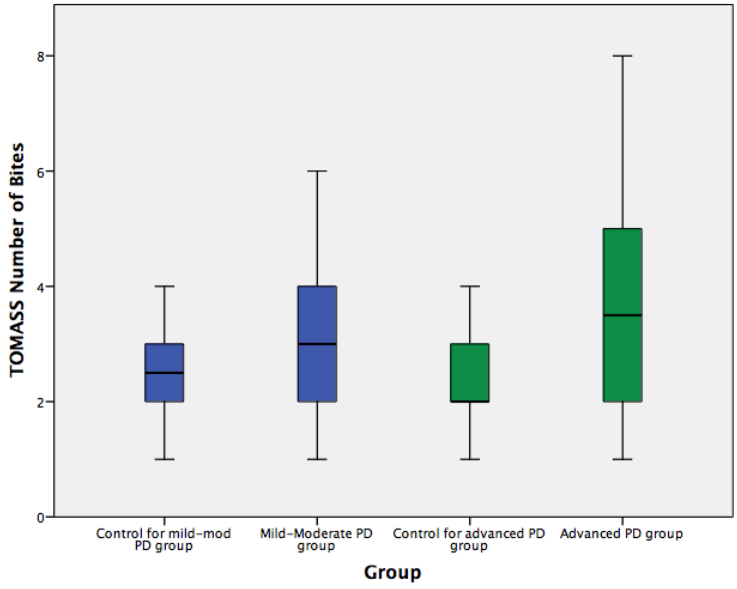


Figure 6-9 - Bar graphs representing group means for each TWST calculated measure variable

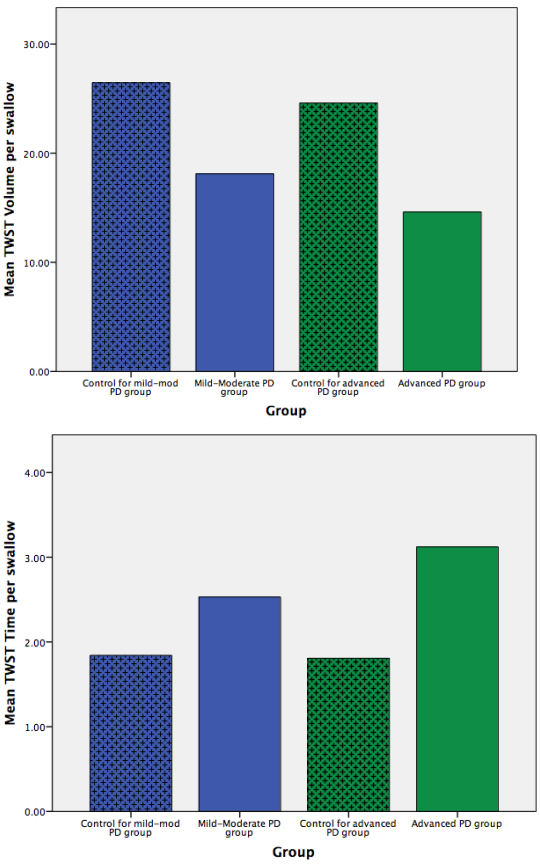


Figure 6-10 - Box and whisker plot representing distribution of Volume per Swallow for the TWST across groups

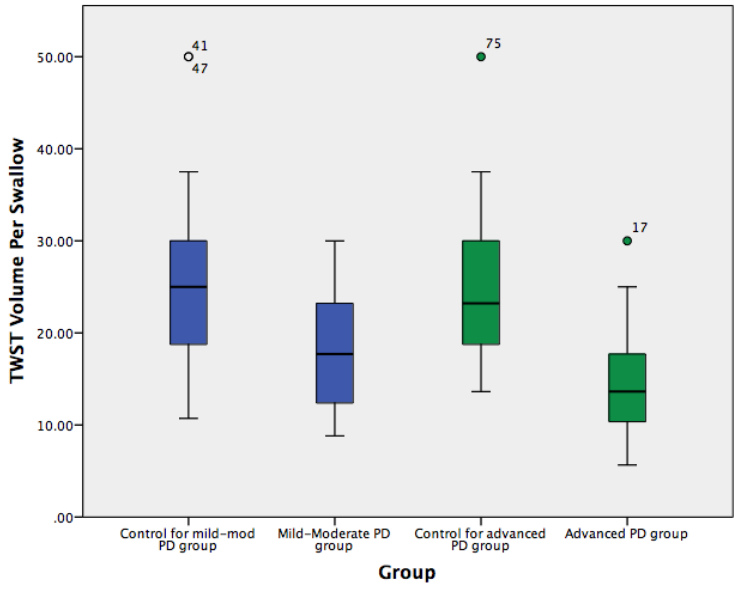


Figure 6-11 - Box and whisker plot representing distribution of Volume per Time for the TWST across groups

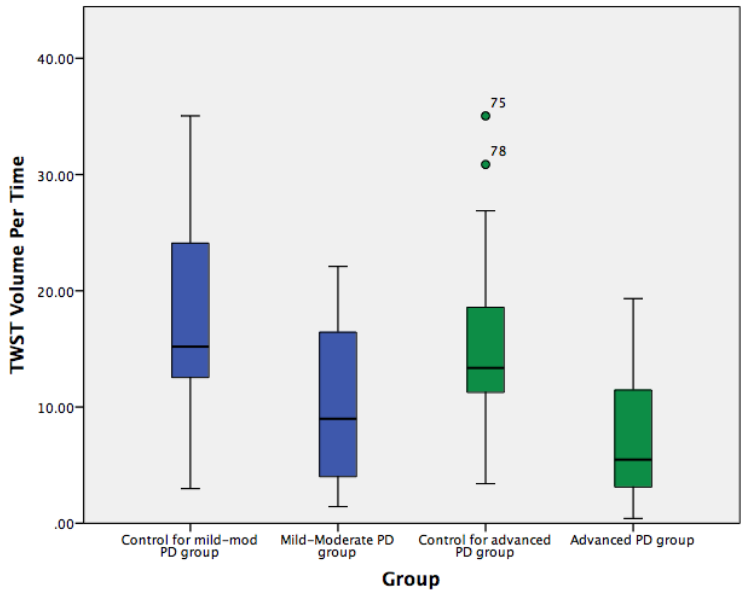


Figure 6-12 - Box and whisker plot representing distribution of Time per Swallow for the TWST across groups

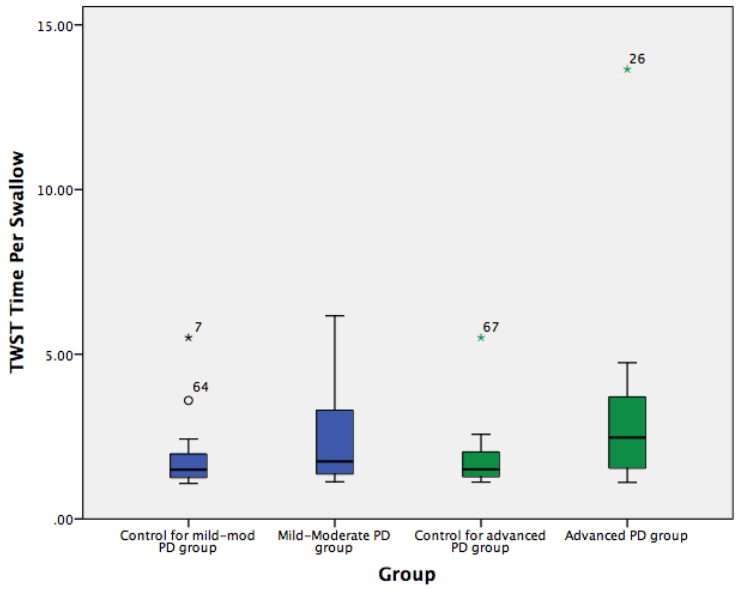
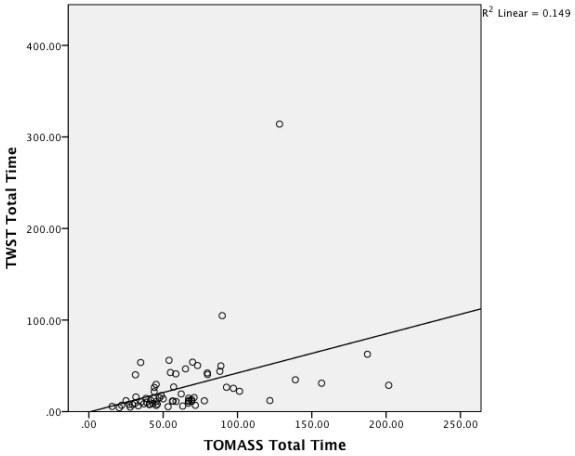
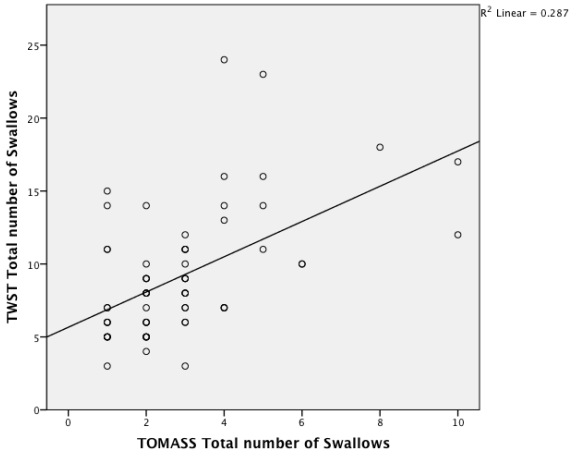


Figure 6-13 - Scatter plots representing the relationship between comparable TWST and TOMASS variables





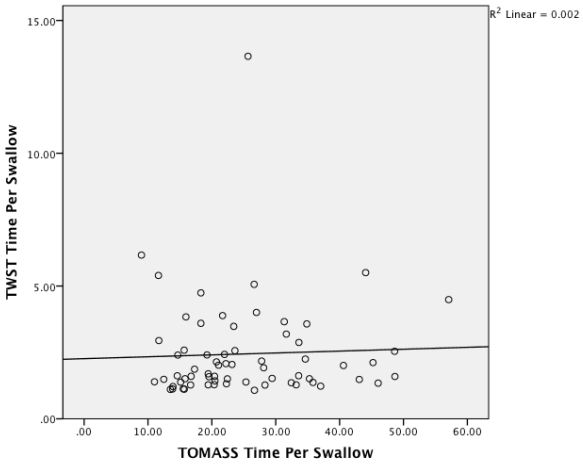


Figure 6-14 - Scatter plots representing the relationship between comparable total EAT-10 score and TOMASS variables